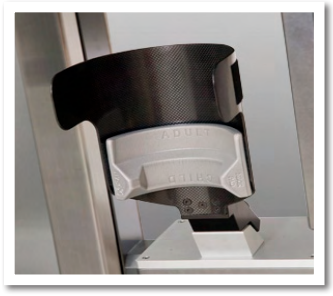
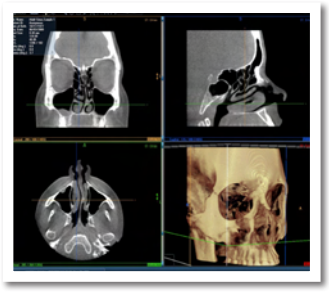
MiniCAT™

USER MANUAL





XORAN®

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1.0 READ THIS FIRST

This section contains important safety information about using your MiniCAT™.

1.1 Safety Guidelines

Although several safety considerations were made in the design, no amount of safety features can completely eliminate the risk associated with X-ray radiation. Improper use may result in injury.

Emergency Stop:

In the event of an emergency (i.e. any moving component collides with any parts of the equipment, items in the environment, or that could cause physical injury to the patient), the operator should utilize the **Emergency Stop (E-Stop)** button to turn off the power to all moving parts in order for the patient to be safely removed from the machine.

Patient E-Stop

Operator E-Stop

All persons operating or occupying the area around the scanner must be properly trained on the principles of radiation safety. The persons authorized to operate the equipment will be properly trained by Xoran Technologies on the principles of operation. Operators of the equipment must ascertain the regulatory requirements and the risks associated with the application of X-ray radiation to patients.

The use of protective devices, such as radiation barriers and protective aprons, are always recommended. Consult with a health physicist or other radiation protection expert to determine the

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appropriate radiation protection devices and practices.

Radiation Safety

The gantry is self-shielded to an extent. However, no design can guarantee that all X-ray radiation is shielded. Therefore, we recommend that additional radiation protection devices are utilized when operating the equipment. A health physicist, or other radiation protection expert, should evaluate the proposed areas in which the MiniCAT™ will be used to determine the radiation protection measures that must be taken.

The MiniCAT™ is equipped with an operator control box that allows for the initiation of a scan while the operator is at a safe distance behind a protective barrier. The operator control box also contains an emergency stop button to terminate X-ray radiation and all powered motion of the equipment in the case of an emergency.

Testing or calibration should never be performed while a patient is positioned in or near the scanner. The operator should utilize the appropriate radiation protection devices while testing or calibrating the equipment.

No attempt should be made to move, adjust or manipulate the scanner or patient during image acquisition. This could result in unnecessary radiation exposure, injury to the patient and/or damage to the equipment.

Caution: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed. Unauthorized use is prohibited. Xoran Technologies LLC is released of all responsibility and indemnity for injury that may result from X-ray radiation or the improper use of the device.

- It is the responsibility of the user to learn about X-ray radiation health risks and to adopt and follow proper X-ray radiation safety policies and procedures before operating the

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MiniCAT™.

- All federal and state regulations pertaining to radiation safety must be observed.
- Please refer to your state radiation safety regulations for specific requirements about the safe and proper use of the scanner.
- Stand behind the operator's barrier when using X-ray.
- Lead-shielded aprons and dose monitoring badges may be required.

ALARA

The principle of **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA) has been implemented into the imaging protocols of the MiniCAT™ and this principle shall be exercised by the user at all times. In this way, unnecessary exposure to radiation can be avoided. ALARA principles shall be exercised by the user at all times. Only required personnel should be in the room when the scanner is in use.

Personal Dosimetry

The purpose of a radiation dosimetry program is to measure the radiation dose equivalent from occupationally exposed radiation workers. You must check with your state radiation safety program to ascertain your state's specific radiation dosimetry requirements.

X-Ray Warning System

When the MiniCAT™ is in use and X-rays are being emitted, you will see a yellow flashing light (located on top of the operator's console) complemented with an audible chirping sound. In addition, it is possible to install external warning lights and/or audible alarms when the X-ray source is enabled in ready state. Call Xoran Customer Service to learn more about these options if required in your area.

Door Interlock System

The MiniCAT™ is equipped with provisions for an optional door interlock circuit. This type of circuit shuts off power to the X-ray source when the door is opened. Call Xoran Customer Service to learn more about these options if required in your area.

Extension Cords / Cables:

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Do not use any extension cords which have not been provided with the MiniCAT™. Use only the interface cables provided with the MiniCAT™. Do not alter the cabling configuration.

Additional Software and Accessories:

Do not connect any items or equipment to the MiniCAT™ which are not part of the system or install any additional software. Either of these actions can cause the system to malfunction and will result in voiding your warranty.

Disposal

Follow local regulations on disposal of waste parts. The X-ray source assembly, image sensor and all electronic circuits should be regarded as non-environmental friendly waste product and should be disposed of in such a way as to minimize the hazard to the health of personnel and the value of property and the community.

Instructions, Training, Use

The MiniCAT™ shall be used, supervised or directed by an individual who is competently aware of the potential hazards involved from ionizing radiation and who is capable of minimizing these hazards. Xoran provides comprehensive training and support for MiniCAT™ users. Xoran accepts no responsibility for the misuse of a MiniCAT™. The user is responsible for compliance with their state's regulation for owning and operating a CT scanner.

Note: Health Canada does not permit the use of the MiniCAT CT scanner for imaging pregnant or pediatric patients.

Note: The best practice is to consult with a qualified medical physicist to ensure safety and compliance. Feel free to contact Xoran Customer Service for assistance in locating an appropriate medical physics professional in your area. 1-800-70-XORAN (800-709-6726)

1.2 Table of Symbols

The following symbols can be found in this manual and on the equipment.

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Symbol	Description
	Type B Applied Part
	Electric Shock, High Voltage: This symbol alerts you to the presence of uninsulated dangerous voltage inside the enclosure -- voltage that may be sufficient to constitute a risk of shock.
	Protective Earth, Ground: Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade."
	Attention: Consult accompanying notices and/or warnings.
	X-ray Caution: These symbols indicate the presence of X-ray radiation. This X-ray device may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.
	Pinch Point: This symbol alerts you to the potential for injury due to moving mechanical parts. Keep hands clear during operation.
	X-Ray Focal Spot: This symbol appears on the X-ray tube head, showing the approximate location of the X-ray focal spot.

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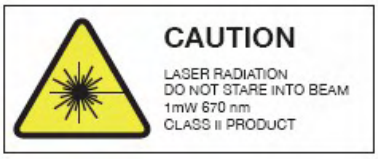
Symbol	Description
	**Class II Laser:** This symbol alerts you to the presence of Class II laser light. Do not stare into the beam.
	Laser Alignment Symbol:
	Electrostatic Sensitive Symbol:
	Circuit Breaker Symbol:
	Patient Chair Symbol:
	Emergency Stop Symbol:

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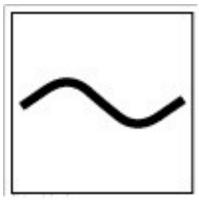
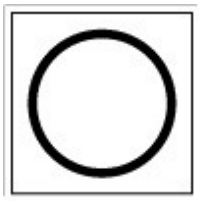
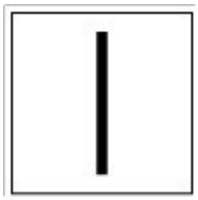
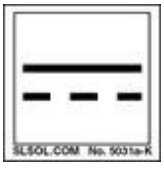
Symbol	Description
	Chair Elevation Symbol (Up / Down):
	Patient Symbol:
	**AC Power Symbol:**
	**Power Symbol (OFF):**
	**Power Symbol (ON):**
	**DC Power Symbol:**

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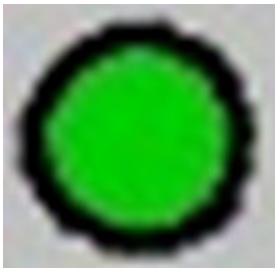
Symbol	Description
	**Medical Grade Power Cord Symbol:**
	Non-Ionizing Electromagnetic Radiation Symbol:
	Serial Connection Symbol:
EC REP	**RMS UK, Ltd., Somerset, BS48 4NU United Kingdom**

1.3 Electromagnetic Interference

The MiniCAT™ has been tested and found to comply with the limits for Class A equipment pursuant to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a commercial environment. The MiniCAT™ generates, uses and can radiate electromagnetic energy. If the MiniCAT™ is not installed and used in accordance with these instructions, it may cause harmful interference to surrounding equipment.

MiniCAT™ is intended for use in an electromagnetic environment specified below. The user of the MiniCAT™ should ensure that it is used in such an environment.

Immunity / Test	Electrostatic Environment Guidance
Electrostatic Discharge	Compliant to +4 kV. Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.

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<table>
<tr><th>Immunity / Test</th><th colspan="3">Electrostatic Environment Guidance</th></tr>
<tr><td>EFT and Surge</td><td colspan="3">Electrical power quality should be that of a typical commercial or hospital environment. See Electrical Power Requirements in section 10.6.</td></tr>
<tr><td>Voltage Dips/Dropout</td><td colspan="3">Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the equipment be plugged into an uninterruptible power supply (included). See Electrical Power Requirements and Apparent Resistance of Supply Mains in section 10.6.</td></tr>
<tr><td>Conducted RF</td><td colspan="3">Portable and mobile communication equipment should be separated from the MiniCAT™ by no less than 19 feet (6 meters).</td></tr>
<tr><td>Radiated RF</td><td colspan="3">The MiniCAT™ is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the MiniCAT™ as recommended below, according to the maximum output power of the communications equipment.
<table>
<tr><th>Maximum Output Power
(Watts)</th><th>Separation
(150 kHz to 800 MHz)</th><th>Separation
(800 MHz to 2.5 GHz)</th></tr>
<tr><td>0.01</td><td>15 in (38 cm)</td><td>30 in (76 cm)</td></tr>
<tr><td>0.1</td><td>15 in (38 cm)</td><td>30 in (76 cm)</td></tr>
<tr><td>1</td><td>46 in (117 cm)</td><td>8 ft (2.4 m)</td></tr>
<tr><td>10</td><td>12 ft (3.7 m)</td><td>24 ft (7.3 m)</td></tr>
<tr><td>100</td><td>38 ft (11.7 m)</td><td>77 ft (23.4 m)</td></tr>
</table>
Note: Field strengths from transmitters, as determined by an electromagnetic site survey, should be less than the compliance level of 3 V/m.</td></tr>
</table>

If the MiniCAT™ is suspected of causing harmful interference to other surrounding equipment, the user is encouraged to try to correct the interference by one or more of the following methods:

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- Turn the MiniCAT™ off and on to verify that the interference is coming from the MiniCAT™.
- Move the other equipment further away from the MiniCAT™.
- Connect the other equipment into an outlet on a circuit different from that to which the MiniCAT™ is connected.
- Contact Xoran Customer Service for additional assistance.

1.4 Cleaning and Service

Cleaning Schedule

It is recommended that the equipment be cleaned and disinfected in the following manner:

Between Patients:

- Clean patient head holder with alcohol. **Do not spray.**

Daily:

- Clean dust from surfaces by wiping with a dry or slightly damp cloth. **Do not use any chemicals on any part of the MiniCAT™.**

Monthly:

- Check for defective X-ray indicator lights and sounds.
- Gently vacuum dust from fans behind acquisition workstation and server (if applicable).
- Open server front panel and gently vacuum dust accumulation (if applicable).

Service and Maintenance

It is recommended that the equipment be inspected and serviced annually. Inspection and service must be performed by Xoran Technologies LLC or other technician licensed and qualified to service this equipment. Circuit diagrams, component parts lists, descriptions and calibration instructions can be made available upon request.

Service/preventative maintenance for the first year of equipment operation is covered by Xoran Technologies under the equipment warranty. Ongoing service and preventative maintenance can be purchased under a service agreement with Xoran Technologies.

It is the responsibility of the user to ensure that the equipment is maintained in compliance with the manufacturer recommended maintenance schedule. The manufacturer and the assembler/installer cannot be held responsible for the failure of the owner/user to have the manufacturer's recommended

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maintenance performed.

Maintenance Schedule:

Computer Maintenance	• Remove dust and inspect (Annually) • Replace Video Card (Every 4 years)
UPS Maintenance	• Remove dust and inspect (Annually) • Replace batteries (Every 3 years)
MiniCAT™ Maintenance	• Clean and inspect (Annually) • Replace Head Select IM483 fan (Annually) • Replace DC Power Supply (Every 5 years) • Replace Receptor Cooling Fan (Every 5 years) • Chair and laser alignment (Annually)
Electromechanical Safety Test	• Line Voltage Test (Annually) • Chassis to Ground Test (Annually) • Leakage Current Test (Annually)
Source Maintenance	• Perform Source check and recalibrate as needed (Annually)
Application Maintenance	• Geometric Calibration (Annually) • Shutter Calibration (Annually) • Water Attenuation Calibration (Annually)
Quality Control Tests	• CT Number of Reference Materials (Annually) • Spatial Resolution (Annually) • CT Number and Standard Deviation of Water (Annually) • Artifact Test (Annually) • Uniformity Test (Annually) • Contrast Scale (Annually) • Image Noise (Annually) • Nominal Tomographic Section Thickness and Slice Sensitivity Profile (Annually)

1.5 Data Backup

Every effort has been made to ensure that patient data is stored safely on the MiniCAT™. However, it is recommended that periodic backup is performed to prevent data loss in the event of catastrophe or system failure. It is the user's responsibility to ensure adequate data backup is performed.

Call Xoran Customer Service for recommendations on how to perform data backup most effectively.

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1.6 Regulatory Compliance

MiniCAT™ has been tested and/or evaluated against and found to be compliant with the following standards/requirements:

- IEC 60601-1:2003-04-25 (ED.1) with Revisions up to 2003/06/30:
- IEC 60601-1-1:2000 Collateral Standard-General Requirements for Radiation Protection for Diagnostic X-ray Equipment
- IEC 60601-1-2: 2001 + A1: 2004 Class A for Emissions, Immunity for Non Life-Supporting Equipment
- IEC 60601-1-3 1994 Particular Requirements for Safety of X-ray Equipment
- IEC 60601-1-4 General Requirements for Safety-Collateral Standard: Programmable Electrical Medical Systems
- IEC 60601-2-32: 1994 Particular Requirements For the Safety of X-ray Equipment for Computed Tomography
- IEC 60601-2-44: 2001 Particular Requirements For the Safety of X-ray Equipment for Computed Tomography
- CAN/CSA C22.2 No.:601.1-M90 Collateral Standard-Safety Requirements for Medical Electrical Systems

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Equipment Class:

- Protection against electric shock: Class I
- Applied part has degree of protection against electric shock: Type B Applied Part
- Class of equipment against ingress of liquids: Ordinary Equipment, IPX0
- Radiated emissions: Class A
- FDA: Class 2
- Mode of Operation: Continuous operation with intermittent loading

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2.0 INTRODUCTION

2.1 Welcome

Dear Valued Xoran Customer,

Thank you for purchasing the MiniCAT™ scanner.

We designed the MiniCAT™ scanner and the User Manual to be easy to use. This User Manual gives you chronological, step-by-step instructions for operating the scanner. It also provides you with technical specifications of the MiniCAT™ scanner.

To ensure the safe and proper use of your new scanner, please make sure that you read and understand this User Manual before operating the scanner and follow the User Manual's operating and safety instructions when using the scanner. The instructions in this User Manual are meant to supplement your Xoran on-site training, your radiation safety training as required by your State's Radiation Safety Regulations, and your own professional training and expertise.

Customer Service and Support is our first priority. We want to do everything we can to help you use your new MiniCAT™ scanner in a safe and efficient manner.

If you have any questions, please call us at: 800-70-XORAN (800-709-6726). Our Customer Service Engineers will be happy to help you.

Sincerely,

Xoran Technologies LLC
www.xorantech.com

2.2 MiniCAT™ Overview

MiniCAT™ is a compact, upright volume computed tomography system designed for high-resolution, bone window imaging of the sinuses, temporal bones and skull base. MiniCAT™

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provides immediate access to images at the patient's point-of-care resulting in a faster diagnosis and treatment.

MiniCAT Intended Use:

The MiniCAT is an X-ray imaging device that constructs a three-dimensional model of the head and neck from images taken during a rotational X-ray sequence. The
MiniCAT is optimized for the imaging of the maxillofacial complex, temporal bone, and sinuses.

2.3 Online User Manual

The most up-to-date version of this manual can always be viewed online at http://help.xorantech.com/MiniCAT_5.2. Navigate the online manual by clicking chapter headings in the table of contents (on the left). For a PDF copy, click the **convert to PDF** button in the top right-hand corner of the online manual.

Tip: From the MiniCAT™ software, press the F1/HELP key at any time to launch the online manual.

2.4 System Hardware

The following diagram shows the MiniCAT™ system hardware with the main components identified.

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These components will be referred to throughout this manual.

2.5 Other Components

The following is a list of other components that accompany the MiniCAT™. Call Xoran Customer Service for replacements as needed.

Part Number	Description
15234	Phantom Holder
20008	Seat Cushion
20011	Workstation with Keyboard and Mouse
20132	Mouse Pad
15239	Carbon Fiber Head Holder

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Part Number	Description
27276	Head Pads (wedges)
30022	Head Pads (head strap)
30824-01	Broadband Router
30006	Foot Stool
30010	HP 6940 Printer
30013	Pregnancy Sign
30015	Caution Sign
30600	SmartOnline Uninterruptible Power Supply
30231-00	Operator's Desk
30019	Booster Seat
30233-02	Samsung 21.5" LCD Monitor
40025 V5.0	MiniCAT™ Quick Reference Guide v5.0
40026 CD V5.1	MiniCAT™ User Manual v5.1
60038	Phantom Set

Additional MiniCAT Software 'Viewing Stations':

A MiniCAT 'Viewing Station' is a computer that has MiniCAT software installed and is used as an additional client workstation within a Practice or Hospital environment. Viewing Stations can be used for viewing Xoran studies and generating image outputs. Viewing stations are connected to a Xoran server and they retrieve patient data and studies from the Xoran server over local area network.

The following features are available to users on Viewing Stations:

- Search and display patient information
- View Study Files
- Modify window/level, image selection, annotations and perform other available image modification operations

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- Perform image output actions including exporting and printing images and DICOM push

Note: The Xoran server supports up to 5 concurrent connections and up to 20 client connections.

The following features **will not be available** to users on a Viewing Station:

- Acquisition and daily calibration
- Reconstruction of raw Study File data (CPU and GPU)
- Modality Worklist support
- Patient Record Management (creating, modifying and deleting patients)
- Modifying Study Header
- Deleting Study File
- Importing Study Files
- Study File Purge
- User Management

NOTE:

1. **The '3D View' functionality will be assured to function with a Xoran Specified Computer System.**
   Note: A Xoran Specified Computer System will require the user to limit the installation of miscellaneous third party software. Additional software programs installed on your workstation could impact the efficient function of the Xoran 3D View.

2. **The '3D View' option may not work with standard computer systems - minimum computer hardware and software specifications for Viewing Stations are supplied in section 10.6 of this User Manual (Installation Requirements).**

3. **Xoran does NOT assure that 3D Viewing will work, as intended to, on a NON-Xoran Supplied Computer System.**

Note: Only use original components provided with the MiniCAT™. Do not use any other parts or accessories.

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2.6 Quick Reference Guide

Note: This page is a brief overview of the MiniCAT™. Please attend MiniCAT™ training with a qualified instructor, and read the complete MiniCAT™ User Manual before operating the equipment.

PREPARATION

1. Perform a Daily Calibration

- For best results, scanner should be powered on for at least one hour before calibration

Note: Refer to Section 3.2 for System Startup instructions.

- Click **Daily Calibration** from the **Tools** menu (or press the F9/CAL key)

Caution: X-ray radiation emitted. Follow radiation safety protocols.

2. Enter Patient Information

- Enter patient information and click **Save**

SCANNING

1. Select Patient

- From the **Patient Database**, locate and highlight the patient record
- Click **Acquire New** and follow the on-screen prompts

2. Select Procedure

- Create a study title, select the procedure and choose the ordering physician

3. Seat and Position Patient

- Have patient remove jewelry, glasses, hair accessories, etc. from patient's head
- Adjust height of patient chair until ear is positioned as shown
- Use alignment light to position patient based on imaging protocol (see below)

Caution: Laser light emitted. Do not stare into the beam.

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Align top of ear just below wing of head holder

Sinus Scan
Align with high cheekbone

Temporal Bone Scan
Align with tragus

Sinus Scan for GE IGS
Align with corner of eye

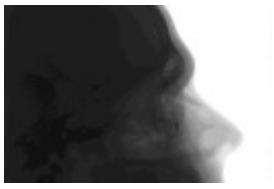
Insert temple wedges squarely and securely on sides of patient's head

Secure patient's head with forehead strap

4. Scan Patient

Caution: X-ray radiation emitted. Follow radiation safety protocols.

- **Scout** confirms patient position

	No Scout Needed	
Sinus Scan Scout	Temporal Bone Scout	Sinus Scan Scout with GE Headset

- Click **Start Acquisition** to initiate the scanning process and follow the on-screen prompts
- When the scan is complete, the gantry will rewind and reconstruction will start automatically

5. View and Export Images

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- The study will open in the *Multi-planar Reconstruction (MPR)* window. This is the default setting for viewing and manipulating reconstructed images. Axial, coronal, sagittal, and 3D views are all visible at once.
- Click **Image Output** from any image viewing window to export images (if applicable)

6. Initiate Scan Transfer to XoranConnect®

- After the acquisition and reconstruction are complete, click **Exit** in the viewer window to initiate scan transfer and allow it to be available on XoranConnect®

Note: Press the F1/HELP key to access the online user manual.

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3.0 STARTUP AND SHUTDOWN

3.1 Emergency Shutdown

In the case of an emergency, the system rotation can be stopped and X-ray emission can be halted by pressing the **Emergency Stop (E-Stop)** button. The operator E-Stop is located on the Operator Control Box on the operator's desk. The Patient E-Stop is located on the Patient Controller which can be held by the patient during the scan.

Patient E-Stop **Operator E-Stop**

When activated, the E-Stop control immediately shuts down the scanner, cutting power to all moving parts and ceasing the emission of X-rays. The operator or patient should press the E-Stop **in case of emergency or system malfunction** where the safety of the patient or operator is at risk, such as:

- Extreme patient motion during acquisition (i.e. standing up).
- Software malfunction (i.e. frames do not appear during image acquisition).
- A person or object enters the gantry path during acquisition

After pressing the E-Stop:

- Have the patient exit the scanner
- Rotate the E-Stop button clockwise to reset the MiniCAT^{TM} system.
- Contact Xoran Customer Service if additional support is required.

After pushing the E-Stop, the overhead gantry can be manually rotated so that the patient can safely

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exit the scanner.

Caution: Turn E-Stop clockwise to reset. It is also recommended to restart MiniCAT™ software after resetting the E-Stop.

3.2 System Startup

Caution: It is recommend that the scanner remain on at all times. If the scanner has been shut down for any reason, please allow one hour for the scanner to warm up before scanning patients to ensure the best quality images.

Both the MiniCAT™ scanner hardware and the workstation must be turned on for the system to function properly.

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Turn on MiniCAT™ Hardware

To turn on the system, push the green **ON** button on the Operator Control Box.

Turn on the Workstation

The workstation computer controls the MiniCAT™ system hardware and software.

Press the power button to start the workstation.

Also, turn on peripheral devices such as the workstation monitor, printer and server (if applicable) at this time.

The Operator Control Box should be located on the operator's desk. The lights on the Operator Control Box represent the following:

POWER: The system is turned on.

READY: The system is ready to perform a scan.

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X-RAY ON: The X-ray source is on (emitting radiation).

FAULT: When lit, this light indicates that the X-ray has timed out. Please contact Xoran Customer Service for assistance.

FAULT: (flashing) When rapidly flashing, this light indicates a hardware initialization problem. Please follow the system shutdown procedure, followed by the system startup procedure. If the problem persists, please contact Xoran Customer Service for assistance.

Note: The same light configuration is on the front overhead cover of the machine (except the fault light). The Yellow **OFF** button on the Operator Control Box can be used to turn off the MiniCAT™ scanner hardware. It is recommended that the system be left on at all times.

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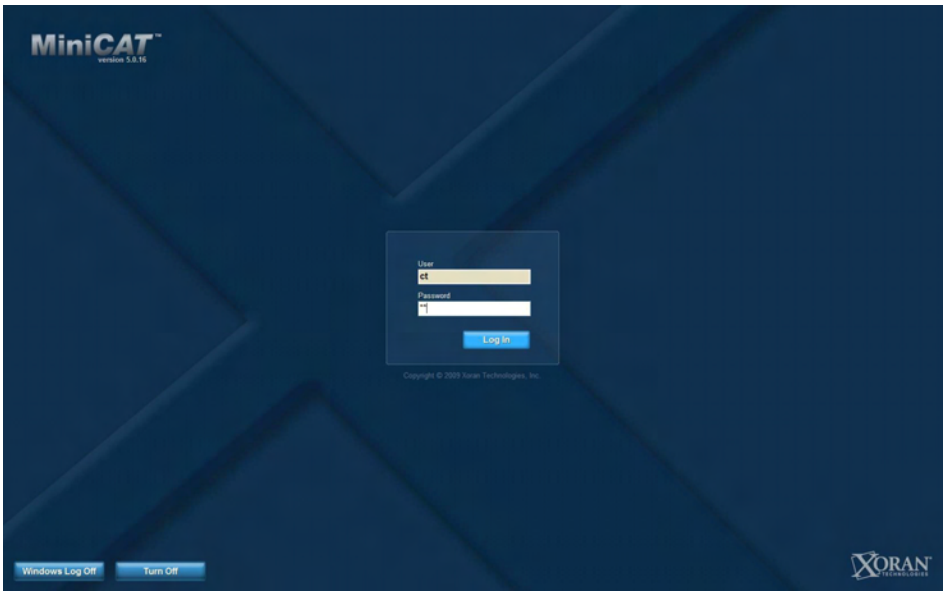
Launch MiniCAT™ Software

1. Double click on the MiniCAT™ icon on the desktop if your system allows access to the Windows desktop. If not, proceed to step 2 below.

2. Enter username and password.



If system has exited to Windows login, type "ct" as your user name and "ct" as the password to return to MiniCAT application.

Upon login, *Patient Database* window will open.

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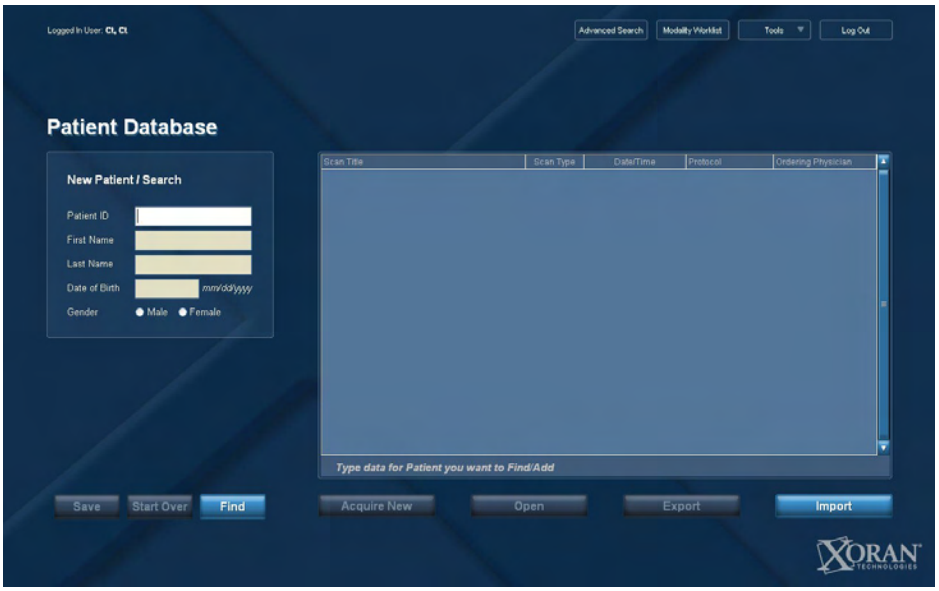

3.3 User Management

Any person operating the MiniCAT™ system is called a user. User information can be managed in the *User Management* window. To launch, select the **User Management** option from the **Tools** menu in the application.

The most common User Management actions are listed below:

- **New User**: From the **User** menu select **New User**. Fill in the user information into the fields.

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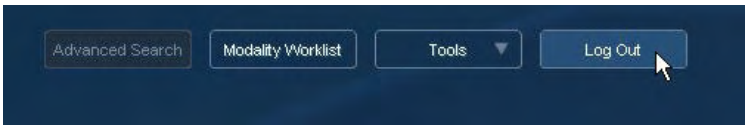
- **Edit User**: Users of the MiniCAT™ system are classified as either an "Ordering Physician" or "Technologist". Each patient study should be assigned to an ordering physician.
- **Delete User**: A user account can be deleted from the system by selecting the selecting a user name and clicking **Delete User**. All information about that user is removed from the system.
- **Active**: Active users have the ability to log onto the system and use the MiniCAT™ software. Clearing the **Active** check box deactivates the user. This prevents this user from using the scanner but preserves the user data for record-keeping and/or future reactivation purposes.

3.4 System Shutdown

Note: It is recommended that the scanner remain on at all times. If the scanner has been shut down for any reason, please allow one hour for the scanner to warm up before scanning patients to ensure the best quality images.

User Logoff

To log out, click **Log Out**.



Turn Off Workstation

Note: All users should Log Out or shut down the workstation when it is not in use due to security of patient data and for best workstation performance.

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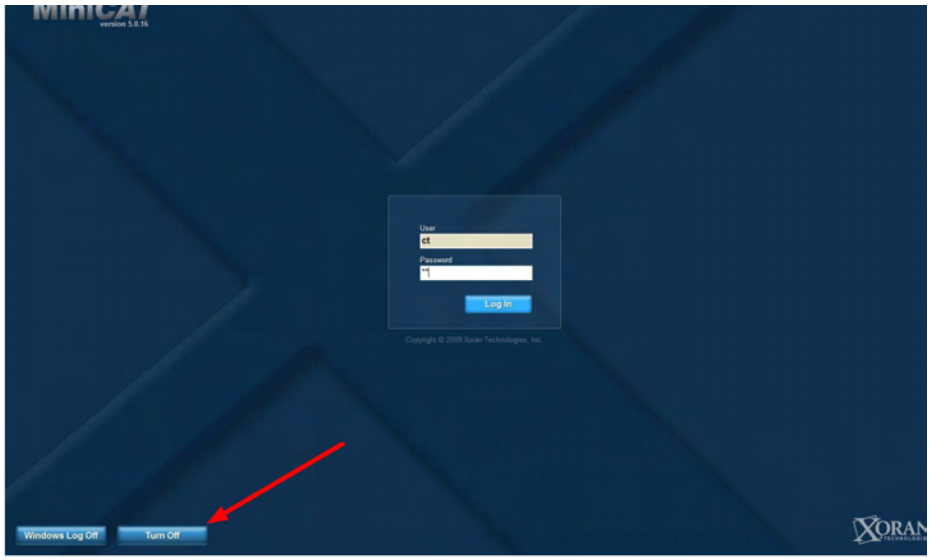
'Turn Off' directly from the Login screen.



Note: The MiniCAT™ workstation will automatically reset every eight hours of inactivity.

Turn Off Scanner

To turn off the scanner, push the yellow **OFF** button on the Operator Control Box. It is safe to leave the scanner on continuously.

3.5 Uninterruptible Power Supply (UPS)

The MiniCAT™ system is equipped with an Uninterruptible Power Supply (UPS) which contains a backup battery with enough capacity to complete one scan with reconstruction. If the facility power

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goes out while a scan is in progress:

- The system will continue to be powered by the UPS battery.
- The scan in progress will complete as usual.
- No information will be lost.
- The UPS will beep indicating that the battery is being consumed.

Note: When the scan is complete, it is recommended that the system be shut down and the main circuit breaker turned off until continuous power is restored. A new scan should not be initiated on battery power.

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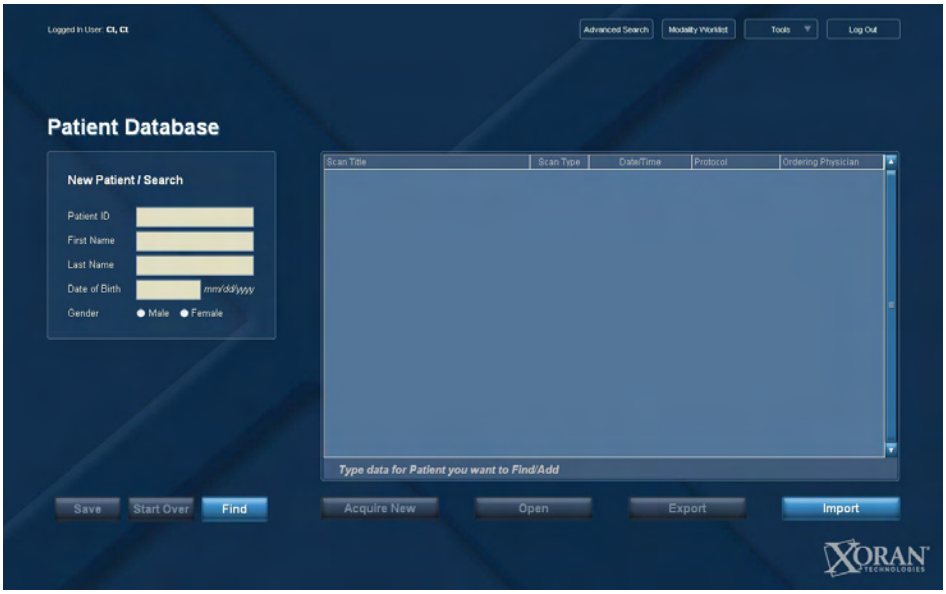
4.0 PATIENT DATABASE

The Patient Database is the user interface to patient records and studies.

4.1 Patient Database

The *Patient Database* window is automatically opened when the MiniCAT™ software application is launched.



Note: The *Patient Database* window will close and revert back to the login screen after two hours of inactivity.

4.2 Enter New Patient

1. To enter a new patient, click **Start Over** in the lower-left portion of the *Patient Database* window.

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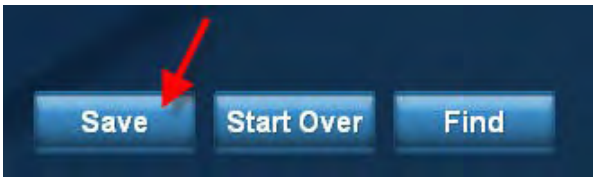
2. Enter patient data in the fields.

3. After entering the information in the required fields, click **Save** on the bottom left of the screen.



4.3 Find Existing Patient

1. To find an existing patient, click **Start Over**. The **Find** button will be enabled and the patient data fields will become blank.

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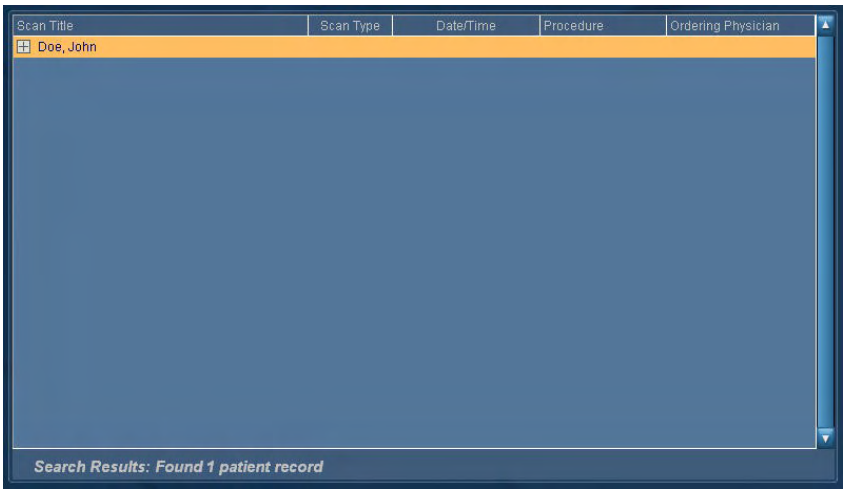
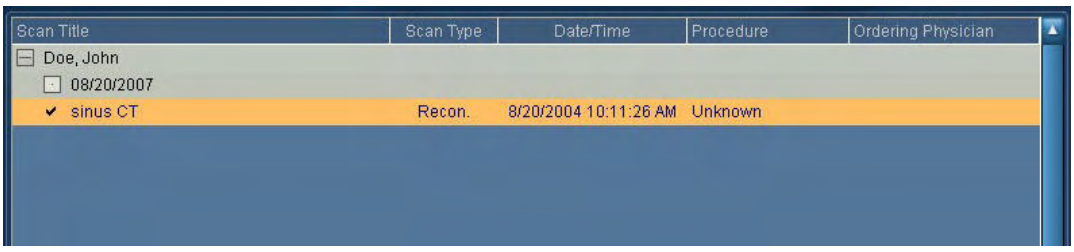
2. Patient records can be searched by name, patient ID, or birthdate. Enter any known information in the patient data fields. For example, type the first few letters of the patient's last name.

3. After you enter your search criteria, click **Find**. A list of matching patients will be displayed.



4. Click on the **[+]** to view studies listed under this patient's name.



There are three types of study files. They are described below.

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Study File Type	Description
Scout	A Scout is the single X-ray image that is used to ensure that the patient is properly positioned for the scan.
Raw	Raw data is a sequence of images collected by the MiniCAT™ system during an acquisition. This raw data is reconstructed using a tomographic algorithm to create 3D imagery.
Recon.	The final result is known as the Reconstruction. This 3D volume imagery can be viewed as a series of coronal, sagittal or axial slices, as well as in many other ways.

5. To open a study for viewing, double-click on its title.

Note: Refer to Chapter 7 for more information on viewing patient studies.

4.4 Advanced Search

Patient studies may also be searched by ordering physician, imaging protocol, or a range of dates when the studies were acquired.

1. Click **Start Over** in the *Patient Database* window.

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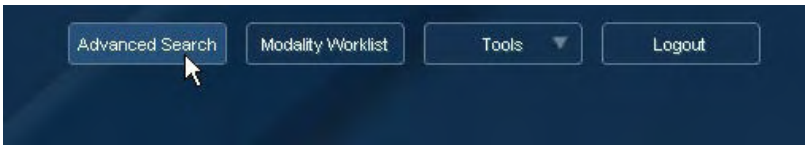
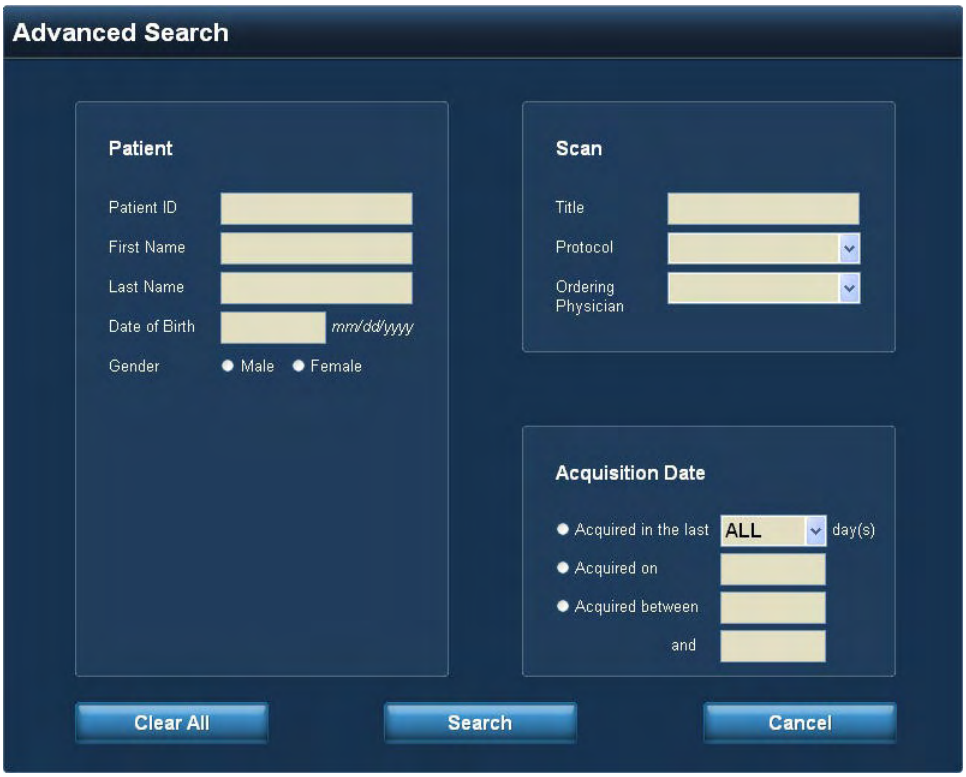
2. Select the **Advanced Search** option from the main menu.



3. Enter search criteria into the *Advanced Search* window and click **Search**. A list of matching patients will be displayed.



3. Click on the **[+]** to view studies listed under this patient's name in the Patient Database.

4. To open a study for viewing, double-click on its title.

Note: Refer to Chapter 7 for more information on viewing patient studies.

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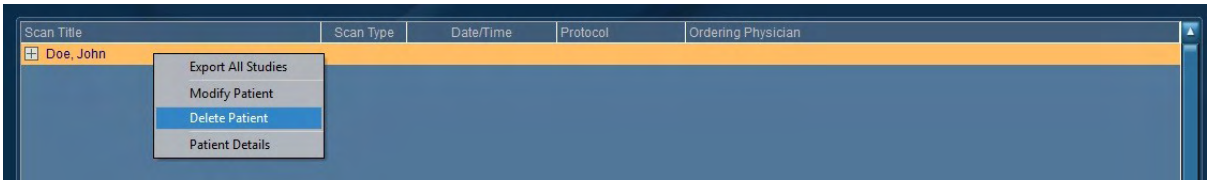
4.5 Delete Patient Record

You can delete a patient record by right-clicking on the patient's name and choosing **Delete Patient** from the drop-down menu.

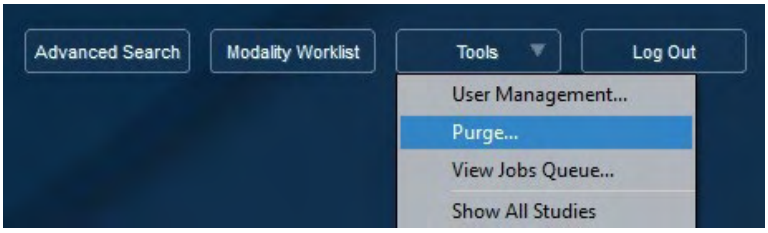


Caution: This action permanently deletes files from your system. Be sure to follow any required procedures for record retention and data backup before deleting patient records.

4.6 Purge Files

To purge unneeded patients and studies in your system, follow these steps:

1. Select the **Purge** option from the **Tools** menu.



2. Specify date interval to purge.
3. Select study type(s) to purge.

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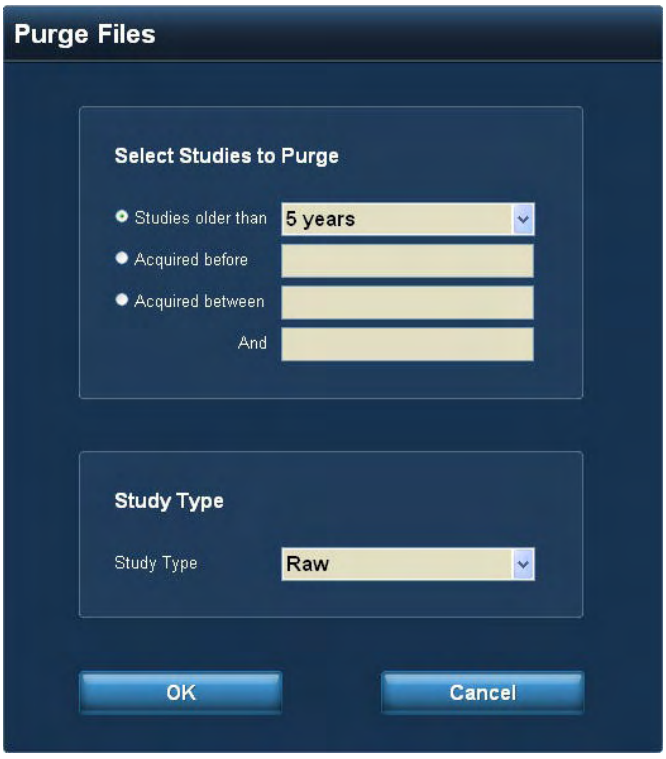
4. Press **OK** to remove the files permanently from your system.



Caution: This action permanently deletes files from your system. Be sure to follow any required procedures for record retention and data backup before purging files.

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5.0 DAILY CALIBRATION

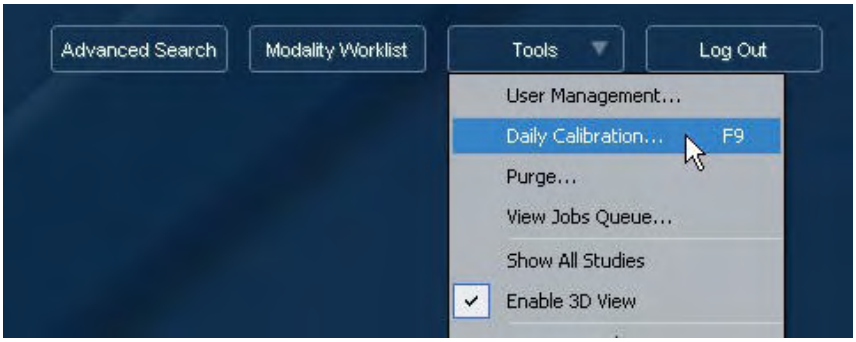
For best image quality, the MiniCAT™ system must be calibrated daily. Calibration should be performed after the system has been powered on for at least one hour. It is recommended to leave the MiniCAT™ system on overnight and calibrate each morning.

Caution: A patient must not be in the scanner during Daily Calibration. X-rays will be emitted during Daily Calibration.

Daily Calibration Procedure

1. **The area between the X-ray source and detector must be free of all objects.** Remove the head holder, phantom holder and any phantom that might be present before continuing.

2a. Select the **Daily Calibration** option from the **Tools** menu.



2b. Alternatively, you can push the F9/CAL key.

3. A message will appear to confirm that all objects have been removed from the field of view. Click **OK** to proceed.

4. A message will appear to start the calibration process. Click **Calibrate** to begin.

5. A message will appear asking you if it is **OK** to turn on the X-ray source. Ensure that you are behind the radiation barrier and click **OK**.

Caution: It is the user's responsibility to ensure that proper radiation safety procedures are followed before X-rays are emitted.

6. Remain behind the radiation barrier until a message appears indicating the calibration is complete. The calibration procedure will take approximately 5 minutes to complete.

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6.0 ACQUIRING IMAGES

6.1 Select Imaging Protocol

Caution: When protocol is selected, the gantry may move. Select protocol before positioning the patient in the scanner.

1. After entering new patient information or selecting an existing patient, click **Acquire New.**

2. The *Patient Confirmation* window will appear. Confirm that the patient selected from the Patient Database is the one you want to scan. Click Acquire New to proceed.

3. The *Acquisition* window will appear.

4. Select the appropriate protocol from the **Protocol** menu. The standard protocol options are as follows:

Protocol	Description
Sinus 20s (600)	20-second imaging protocol with 600 frames (i.e. adult sinus scans).
Sinus 10s (300)	10-second imaging protocol with 300 frames. Scan is faster and lower dose, but image quality will be somewhat reduced compared to Sinus 20s (600) (i.e. adult follow-up sinus scans and/or pediatric scans).
Sinus 10s (150)	10-second imaging protocol with 150 frames is a very low-dose sinus scan (i.e. adult follow-up sinus scans and/or pediatric scans).
T Bone 20s (600)	20-second temporal bone imaging protocol with 600 frames provides higher spatial resolution than the Sinus 20s protocol, and field of view is somewhat smaller.
Water QC	To be used only for specified quality control tests.
Resolution QC	To be used only for specified quality control tests.

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Note: Additional protocols are available for creating images compatible with various image-guided surgery systems. If you have need for a protocol compatible with a specific IGS system, please call 800-70-XORAN (800-709-6726). A Xoran Customer Service representative will be happy to assist you.

5. Select the ordering physician.

- To add a new ordering physician, click the **Add Physician** icon to the right of the Ordering Physician.
- To change the ordering physician on a study, right-click a patient's name in the Patient Database and select **Ordering Physician**.

Note: The *Acquisition* window will close and revert back to the *Patient Database* after 30 minutes of inactivity.

6.2 Prepare the Patient

Note: It is advisable to ask female patients of childbearing age if they are or may be pregnant.

Prior to the scan:

- Instruct the patient to remove jewelry, hair accessories and glasses.
- Instruct the patient to sit upright, relax and face straight ahead.
- The patient can hold the Patient E-Stop control in lap or hands.
- Small lasers will be used for positioning. Remind the patient to close eyes.
- A **Scout** may be taken to verify position.
- A **Dry Run** can demonstrate scanner movement without emitting X-rays.

During the scan:

- Instruct the patient to sit as still as possible for best image quality.
- Instruct the patient to avoid talking, chewing, yawning, swallowing, coughing or slouching.
- Instruct the patient to breathe naturally, moving head as little as possible.
- The scan will be completed in 20 seconds or less.
- The overhead gantry will rotate. The patient should close their eyes to avoid following this

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motion with the head.

- The scanner makes a chirping sound as it performs the scan.
- In case of any problem, the patient can stop the scan by pressing the **Patient E-Stop** button on the Patient Control Box.

After the scan:

- The overhead gantry will rewind when the scan is complete.

6.3 Seat and Position Patient

Caution: Select protocol BEFORE positioning the patient in the scanner.

1. After selecting the protocol and educating the patient, seat the patient in the scanner. Adjust the chair so that the patient's head is positioned in the scanner as shown below.

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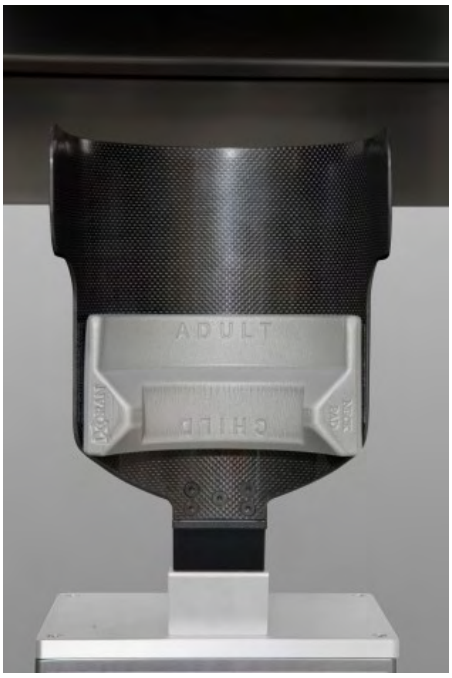
2. The neck pad is positioned in the bottom bracket for adults and the top bracket for pediatric patients. See example below.



3. Use the **Patient Align** arrows on the controller to move the chair up and down.

4. Seat the patient so the neck pad fits comfortably at the curve of their neck. The patient's ears should be approximately 0.5 inches (1 cm) below the sides of the head holder.

5. Instruct the patient to close their eyes.

6. Press the **Alignment Light** button on the controller to turn on the alignment lasers.

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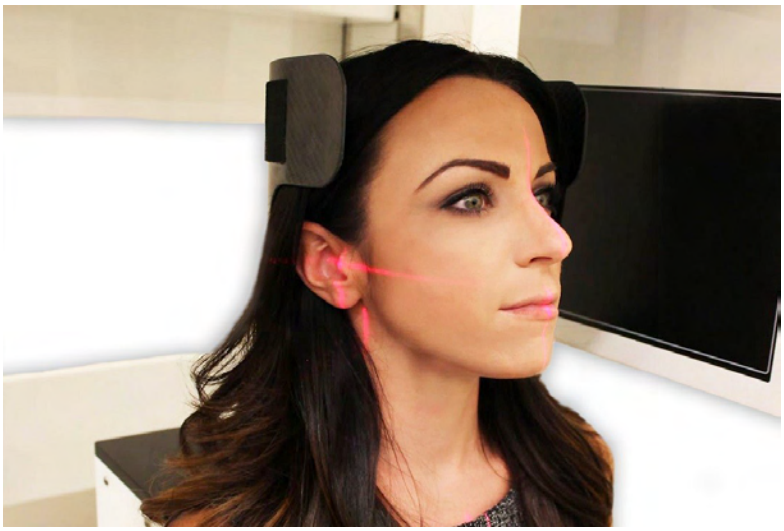
Caution: Laser light emitted. Do not stare into the beam.

- Press button once to turn on the laser for a few seconds.
- Press and hold for three seconds to turn on the laser for five minutes.
- For a Sinus scan, the laser should project the crosshairs on the patient's high cheekbone as shown below.

- For a Temporal Bone scan, the laser should project the crosshairs on the patient's tragus as shown below.



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7. Insert temple wedges squarely and securely on sides of head. Included with each head holder are three pairs of different-sized temple wedges to fit patients of varying head sizes.

8. Secure forehead strap as shown below.

9. Remind the patient to remain still and relax while positioned in the scanner.

6.4 Dry Run and Scout

Perform Dry Run

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The **Dry Run** function rotates the overhead gantry without activating the X-ray source. This function allows the patient to become more familiar and comfortable with the system. This can help to reduce patient motion during the actual CT scan.

1. Check the **Dry Run** box, and the **Acquisition** button will change to **Dummy Acquisition**.

2. A caution will appear. Make sure that nothing is in the path of the rotating overhead gantry.

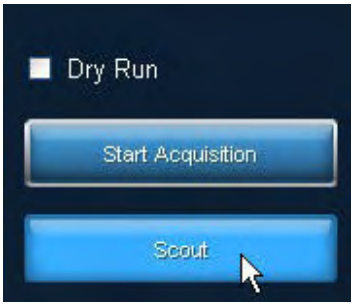
3. Click **OK**, and the gantry will rotate and rewind without firing the X-ray source.

Acquire Scout

A **Scout** is a single lateral X-ray taken to verify that the patient is positioned properly.

Caution: Distances in Scout image are not to scale. Scout should not be used for any purpose other than positioning patient.

1. In the *Acquisition* window, click **Scout**.



2. The following dialogue box will appear:

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Caution: Make sure that all required radiation safety procedures are complied with before proceeding.

3. Remain behind the barrier, and click **OK**. The Scout image will be acquired.
4. Check the Scout image to make sure that the following criteria are met. If the Scout image does not meet these criteria, the patient should be re-positioned.

For sinus scans:

- The sinuses are within the window.
- Patient head appears facing sideways.
- Head is upright - not tilting forward or backward.
- Space exists between the tip of nose and edge of the scout image.
- The top part of the upper lip is included.

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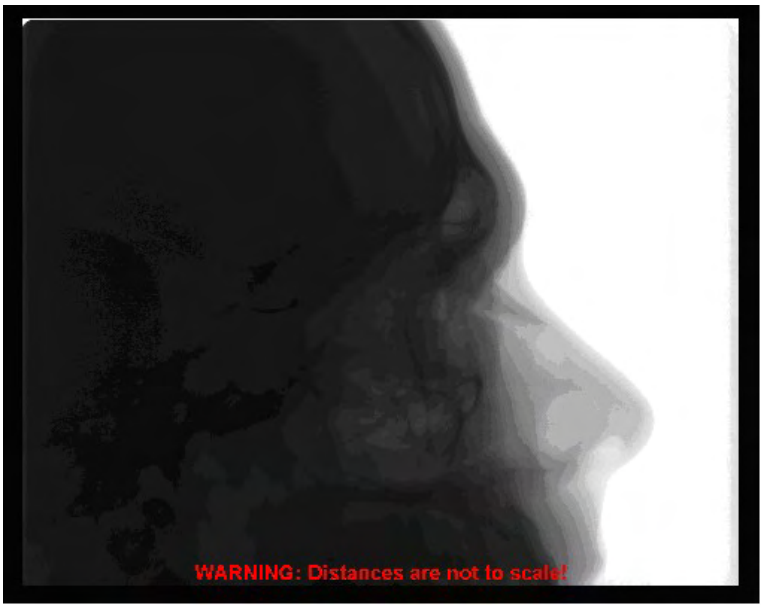
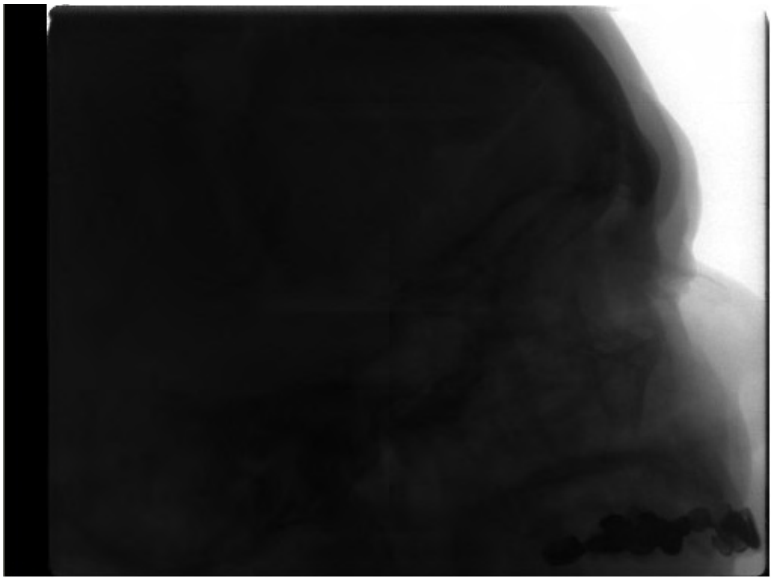
An example of a good sinus Scout View is shown below:



An example of a poor sinus Scout View is shown below. Improper patient positioning is indicated by the visibility of the maxilla and upper teeth, and no space in front of the nose.



For temporal bone scans:

- The temporal bone area is centered in the Scout View image.

Note: For temporal bone imaging, a Scout may not be the best method to assess a patient's positioning. Xoran recommends using only the laser alignment lights.

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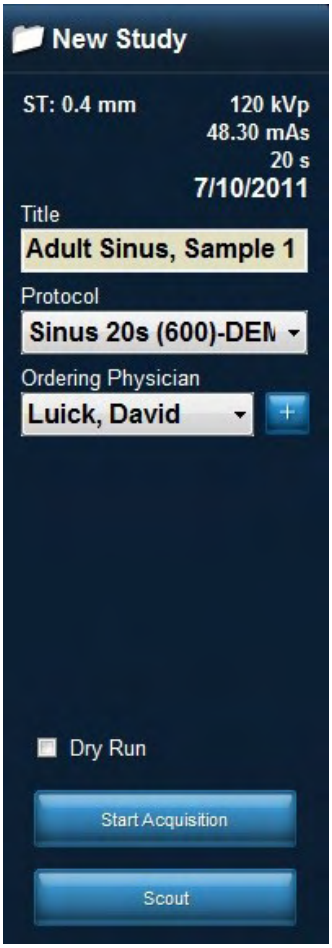
6.5 Start Acquisition

1. After confirming that your patient is properly positioned, you are ready to acquire the CT scan.

2. Stand behind the operator's barrier.

3. Click **Start Acquisition**.



4. Confirm that the scanner has been powered on for at least 60 minutes. Click **OK** to continue, if a confirmation dialogue appears.

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The following message will appear:

Caution: Make sure that all required radiation safety procedures are complied with before proceeding.

5. Remind the patient not to move.
6. Click **OK**. The scan acquisition will begin.
    - The acquisition will take 20 seconds or less.
    - The overhead gantry will rotate around the patient and a series of X-ray images will be acquired.
    - While the X-ray source is turned on, the system will make a chirping sound.
    - When the scan is complete, the overhead gantry will rewind to its original position.

Warning: To stop the scanner in case of an emergency, press the **Emergency Stop (E-Stop)** button.

7. Reconstruction will begin automatically. This takes approximately one minute.

Note: A timer will inform the user when the next acquisition can be performed. Sequential acquisitions must be at least 10 minutes apart.

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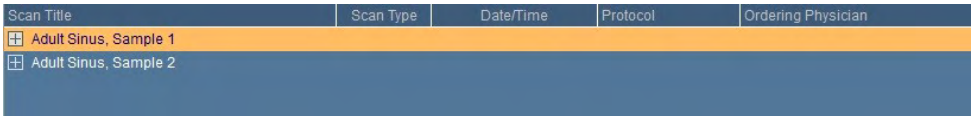
7.0 VIEWING IMAGES

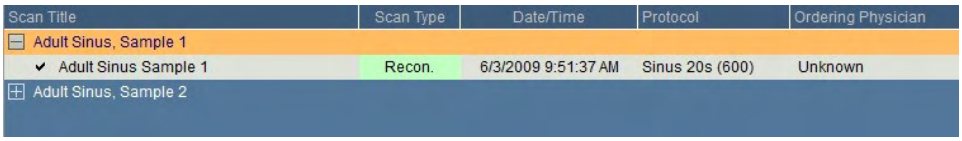
This chapter explains how to open a study, view images using various viewing options and tools, make annotations and select images for output.

7.1 Open Study

1. To open the study from the Patient Database, click the **[+]** next to the patient's name to view records listed under that patient.



2. Double click on the **Recon** study you wish to view.



3. The study will open in the *Multi-planar Reconstruction (MPR)* window. This is the default setting for viewing and manipulating reconstructed images. Axial, coronal, sagittal, and 3D views are all visible at once.

Note: If the 3D window is not in view, refer to Section 7.7 to enable the 3D view.

Tip: An overlay containing patient's name and other information appears in the upper left corner. Press <Ctrl-O> to toggle this text on and off.

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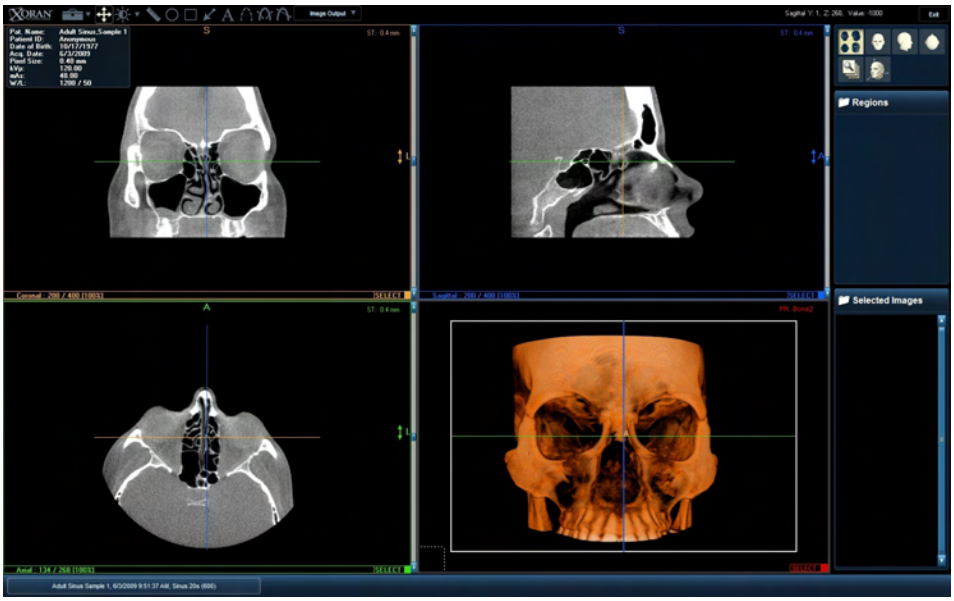

7.2 Viewing Options

The Navigation menu is located in the upper right corner. This menu contains several image viewing options. They are described below.

Image Viewing Option	Description
MPR	Four views are displayed at once. This is a powerful way to navigate the 3D scan volume.
Axial	A series of axial slices are displayed.
Coronal	A series of coronal slices are displayed.
Sagittal	A series of sagittal slices are displayed.
3D	A 3D viewer is displayed.

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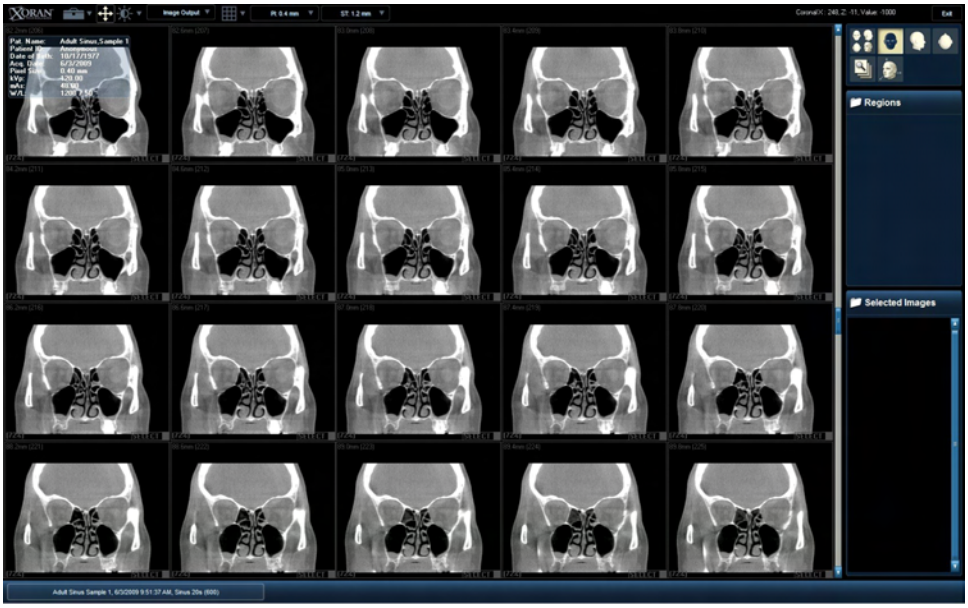
Image Viewing Option	Description
Selected Slices	User-selected slices are displayed (see next section on how to select slices).

To change the view, click on the desired view option in the navigation menu. For example, clicking **Coronal** will present the coronal series of slices as shown below.



7.3 Select Slices

The **Selected Slices** view option allows you to view slices which have been selected by the user. Slices can be selected in order to be printed or exported.

1. Select a view option in the navigation menu (Axial, Coronal, Sagittal, or MPR).

2. Click **SELECT** in the lower-right corner of any image to select the image.

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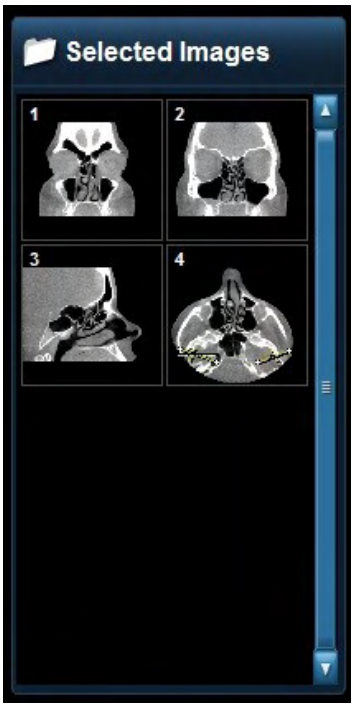
3. When an image is selected, the label will change to the word **SELECTED**.

4. Thumbnail views of Selected Images will appear in the *Selected Images* window.



5. Right-clicking on the **Selected Image** thumbnail will provide a menu of the following options:

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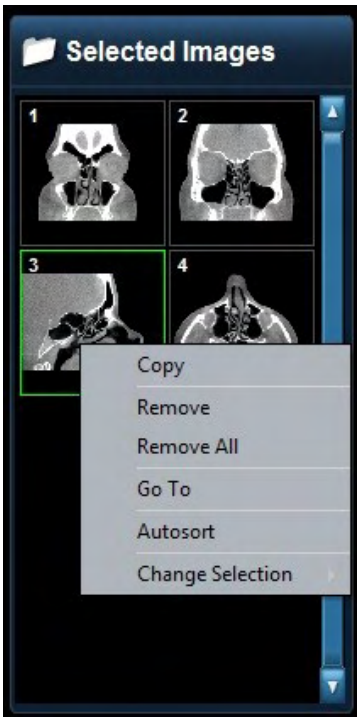

Slice Option	Description
Copy	Copy Selected Image
Remove Selected	Removes a single image from the Selected Images series.
Remove All	Removes all images in the *Selected Images* window.
Go To	Displays the selected slice in MPR view.
Autosort	Orders your selected slices from anterior to posterior.
Change Selection	Allows the user to obtain pre-selected sets of images which are customized by Xoran to fit your imaging needs.

Tip: Hold down the SHIFT key to operate on multiple selected images at once.

Range Indicator

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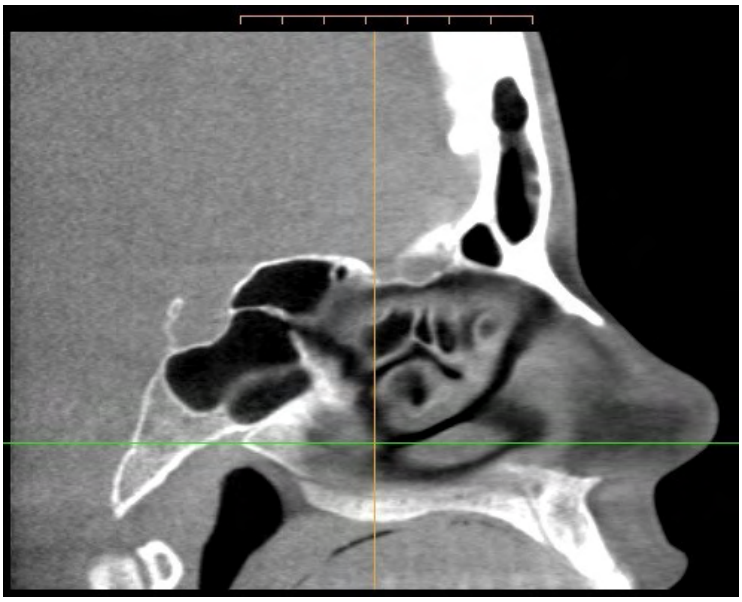
The Range Indicator is a convenient way to select a series of slices. It appears as a colored bar with tick marks representing the locations of selected slices. The spacing between tick marks represents the pitch.



Click on the Range Indicator and drag it side to side to move the entire selected series all at once.

7.4 Viewing Tools

Zoom

1. Select the Pan/Zoom tool from the toolbar.

2. Place the cursor anywhere in the image (except over the colored lines).

- Left-click to zoom in.
- Right-click to zoom out.

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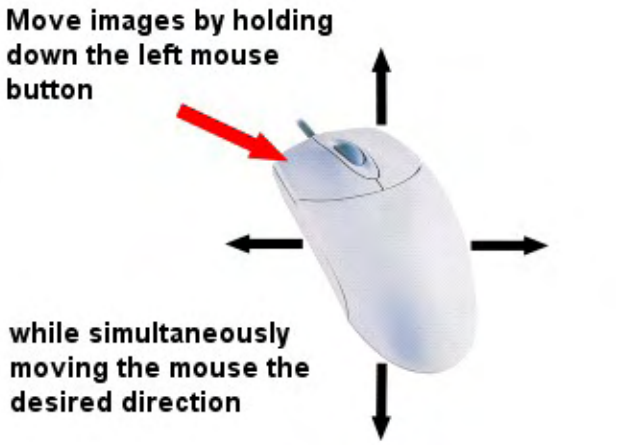
Pan

1. Select the Pan/Zoom tool from the toolbar.

2. Place the cursor anywhere in the image (except over the colored lines).

- Click and hold down the left mouse button.
- Move the mouse to pan the image until desired position is achieved.



Scroll

There are three ways to scroll through the axial, coronal and sagittal slices:

1. The mouse wheel

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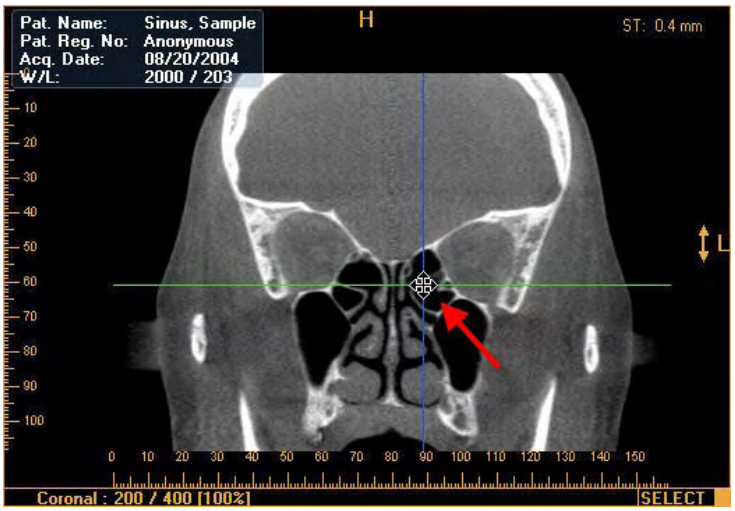
2. The slider

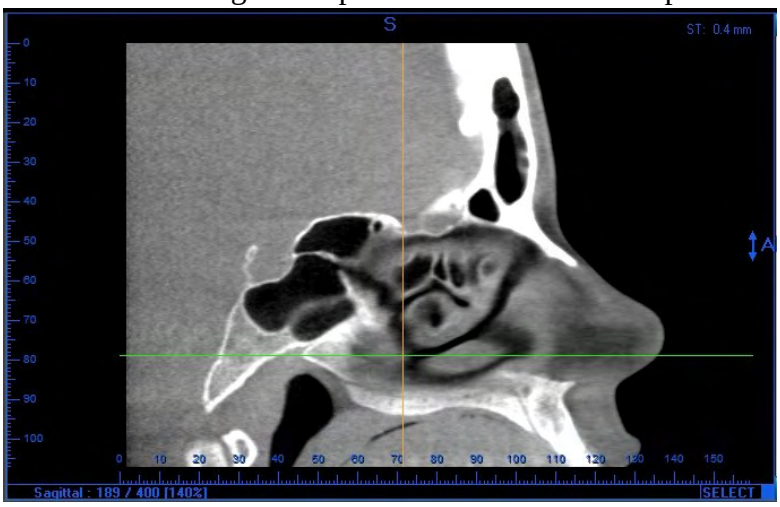


3. The cut-plane lines

Each viewing window has colored vertical and horizontal lines called cut-plane lines. The lines represent the location of the other two views shown in the MPR window.

For example, in the **Sagittal** view shown below:

- The green line represents the **Axial** slice plane.
- The orange line represents the **Coronal** slice plane.



- Cut-plane lines can be moved by clicking and dragging. This causes the images in the other view windows to change.
- Two cut-plane lines may be moved together simultaneously by grabbing the lines at their intersection.

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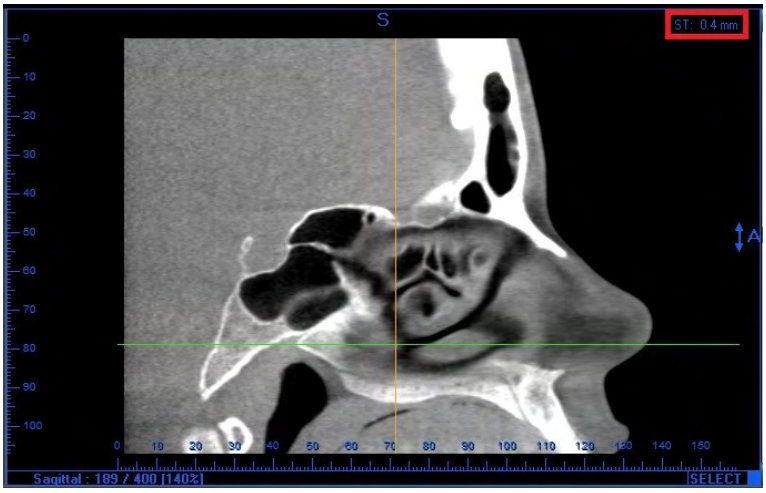
Slice Thickness

The slice thickness is displayed in the upper-right corner of each image in MPR view in a box labeled ST.



Slice thickness can be changed by clicking on the **ST** box and selecting from the list.

- Minimum Slice Thickness (ST) for Sinus: 0.4 mm

Columns

The number of slice images displayed on the screen in **Axial**, **Coronal,** or **Sagittal** views can be altered using the **Columns** pull-down menu.

The following examples show 3 columns (top) versus 5 columns (bottom) in **Coronal** view.

3 columns

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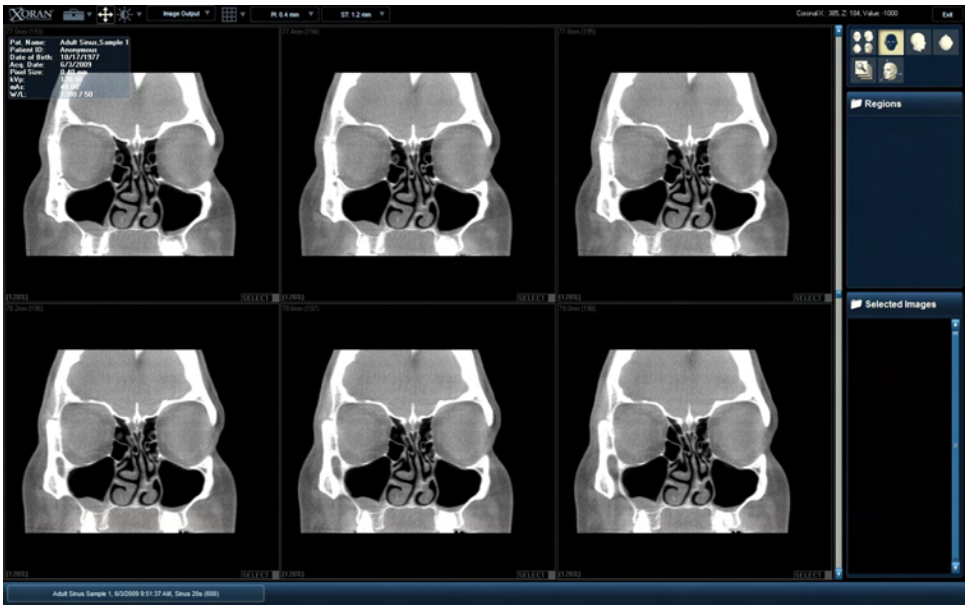
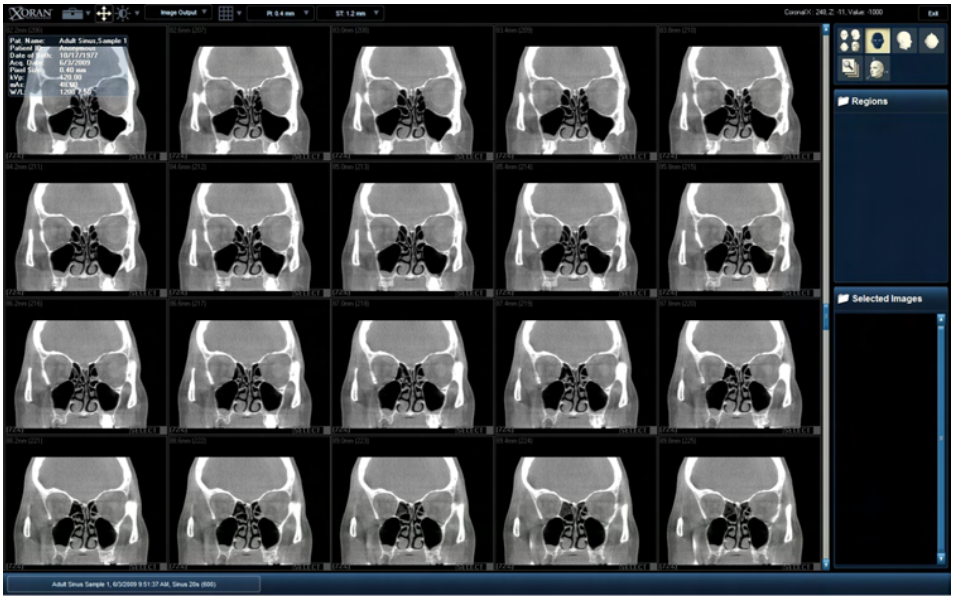


5 columns



Window/Level

The **Window/Level** values determine the brightness and contrast of the displayed image. To adjust:

1. Click on the **Window/Level** icon in the toolbar:

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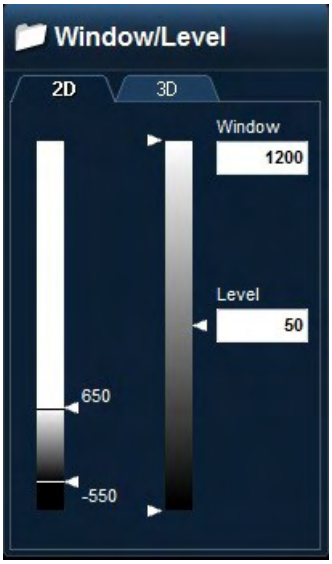
2. The cursor will change to show that you are using the **W/L** tool. Now click and drag anywhere in the image.

    - Window value increases as the mouse is moved to the right of the image and decreases to the left.

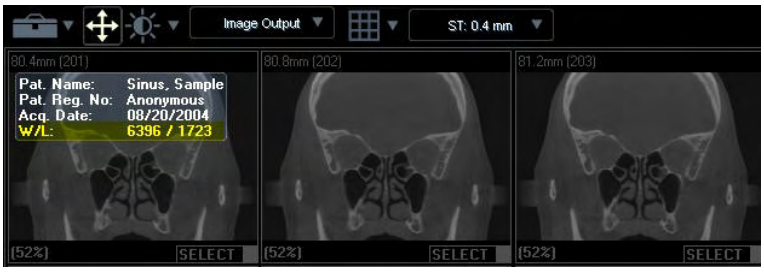
    - Level value increases as the mouse is moved towards the top of the image and decreases towards the bottom.

2b. Alternatively, you can manually input the desired window/level values or adjust the sliders in the Window/Level pane.



Note: 2D and 3D window/level values are independent of each other.

3. The window/level values appear in the patient information overlay, labeled **W/L**.



4. Preset options for window/level can be applied. Click on the down arrow next to the brightness/ contrast icon, and a drop-down menu will appear.

    - Select **Bone** to restore the window and level values to their default values.

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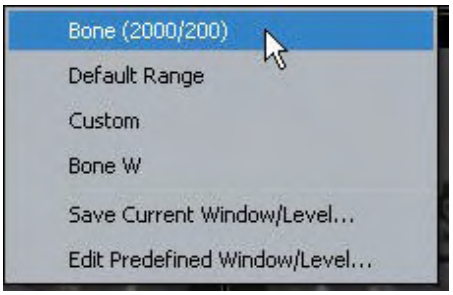
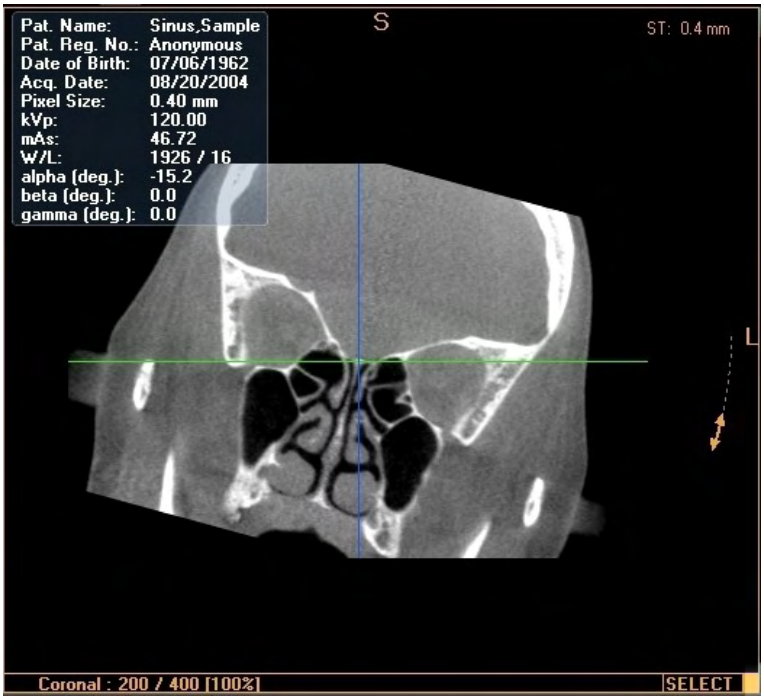


- Select **Set Window/Level** to manually adjust the window and level values for an image and save adjusted values as a new preset.

Rotate

The **Rotate** tool allows images to be rotated in **MPR** view.

- Find the double-ended arrow on the right side of the image.
- Click and drag the arrow up and down to rotate the image.
- Rotation angle adjustments are recorded in the patient information overlay, listed as **alpha**, **beta** and **gamma** angles (values in degrees).



- Images can be restored to their original non-rotated orientations by selecting the **Restore Original Tilt** option from the *Toolbox* menu, or by pressing Ctrl + T.

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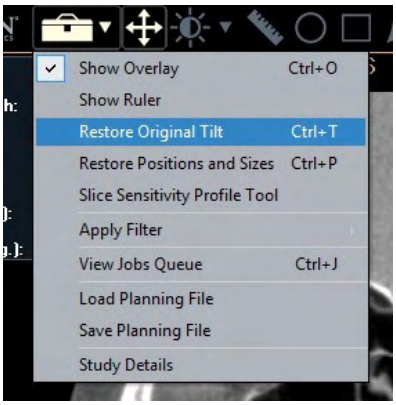

7.5 Annotation Tools

The tools below allow you to make distance measurements and create comment overlays on images. All measurement and annotation tools can be used in any window where images are displayed. To view annotations within a scan, click the appropriate annotation within the **Regions** area.

Distance Tool

In the MPR viewer, the **Distance Tool** measures the distance between two points on an image (in millimeters).

1. Click on the **Distance Tool** icon in the toolbar to activate the tool.

    . Left-click on the starting point of your desired measurement.

    • Click once on each endpoint. Do not hold mouse button down.

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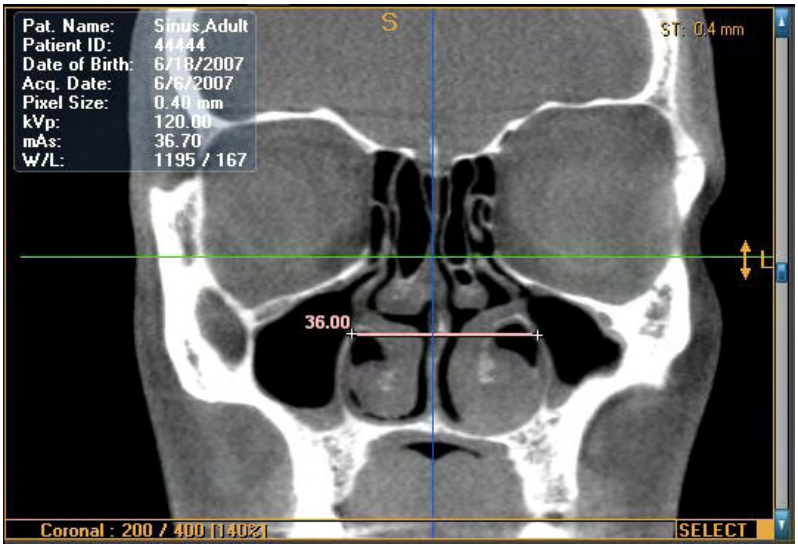
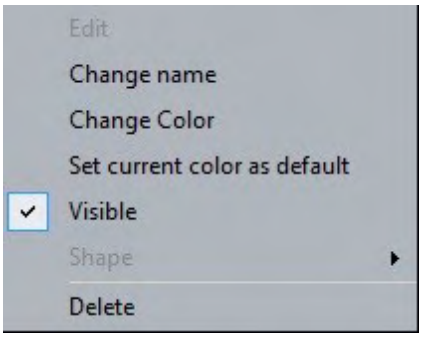
. Move the cursor to the end point of your desired measurement and left-click. A distance value will appear.

Note: The distance values are millimeters.



- Line objects can be moved by left-clicking the line and dragging it to the desired location.
- Line objects can be modified by right-clicking the line. A drop-down menu will appear with the following options:



Line Options	Description
Change Name	Changes the name of the line.
Change Color	Changes the line color.
Set current color as default	Sets the current color of the line as the default color for subsequent lines.

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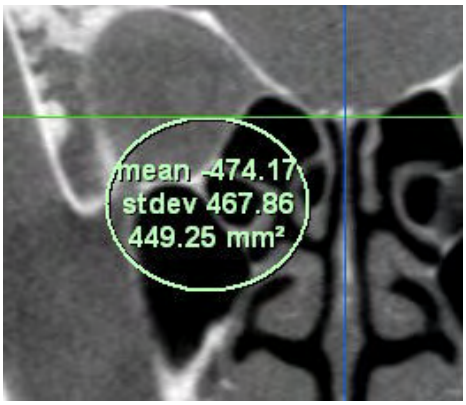
Line Options	Description
Visible	De-selecting this option makes the line disappear from view. Bring the object back to view by right-clicking the corresponding object from the *Regions* menu and selecting **Visible.**
Delete	Deletes the line object.

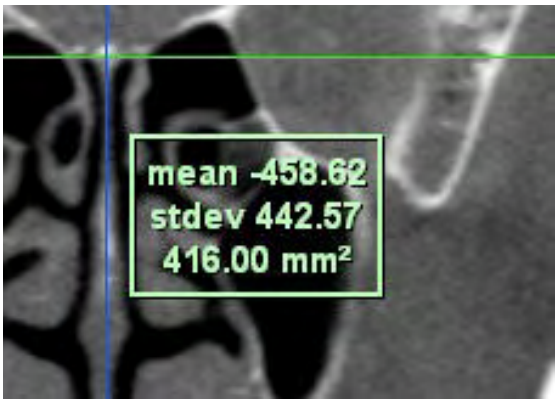
Circle and Rectangle Tools

The **Circle and Rectangle Tools** allow a region of any image to be selected and report statistics of the image region within the shape outline.

1. Click on the **Circle Tool** icon or the **Rectangle Tool** icon in the toolbar to activate the tool.
2. Left-click on the center of the target region.
    - Click once. Do not hold mouse button down.
3. Left-click again on the edge of the target region, and a shape object will appear. The mean, standard deviation and surface area values will appear inside the ellipse.

Note: The units of the mean and standard deviation values are in Hounsfield units





- Shape objects can be moved by left-clicking the line and dragging it to the desired location.
- Shape objects can be modified by right-clicking the line. A drop-down menu will appear with the following options:

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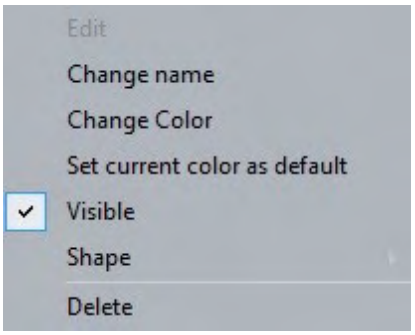

Shape Options	Description
Change Name	Changes the name of the shape.
Change Color	Changes the color of the shape.
Set current color as default	Sets the current color of the shape as the default color for subsequent shapes.
Visible	De-selecting this option makes the line disappear from view. Bring the object back to view by right-clicking the corresponding object from the *Regions* menu and selecting **Visible.**
Shape	Changes the shape to a rectangle, ellipse, circle or square.
Delete	Deletes the shape object.

Text Tool

Text can be added to an image. This simple but flexible tool can be useful for labeling anatomical features or making notes.

1. Click on the **Text Tool** icon or the **Label Tool** icon from the toolbar.
2. Left-click and drag the cursor diagonally on an area of the image where the text box will be located. Click again to release. Double-click on the word **Text** or **Label**, and begin typing.

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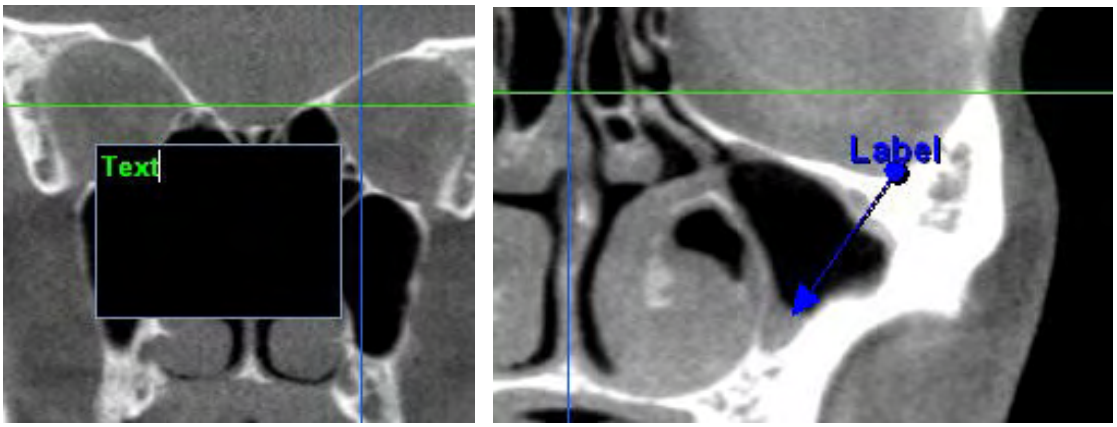
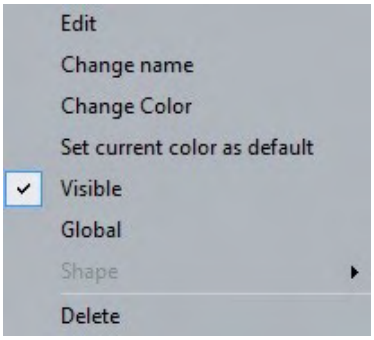


- Text and Label objects can be moved by left-clicking inside the box and dragging it to the desired location.
- Text and Label objects can be modified by either double-clicking inside the box or by right-clicking inside the box. A drop-down menu will appear with the following options:



Text and Label Options	Description
Edit	Edits the content of the text box.
Change Name	Changes the name of the text box.
Change Color	Changes the color of the font.
Set current color as default	Set the current color of the font as the default font color for subsequent text boxes.
Visible	De-selecting this option makes the line disappear from view. Bring the object back to view by right-clicking the corresponding object from the *Regions* menu and selecting **Visible.**

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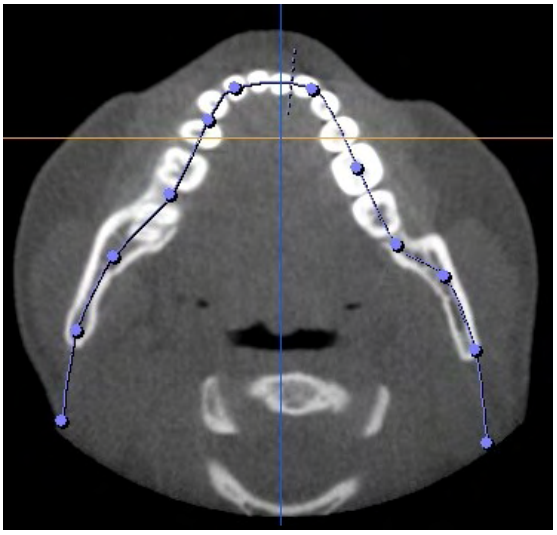
Text and Label Options	Description
Global	Text will be visible on all the other slices in the dataset (within the same viewing window).
Delete	Deletes the text box.

7.6 Oblique and TMJ Tools

The Oblique and Two Points Oblique tools can be used in any plane.

Oblique Tool

1. Click on the **Oblique** icon . When this icon is active, you have the ability to flatten oblique and curved objects into a two-dimensional view.
2. Left-click to deposit points along the desired pathway, and double-click on the last point to end the line. An example is shown below.



3. The following screen will appear:

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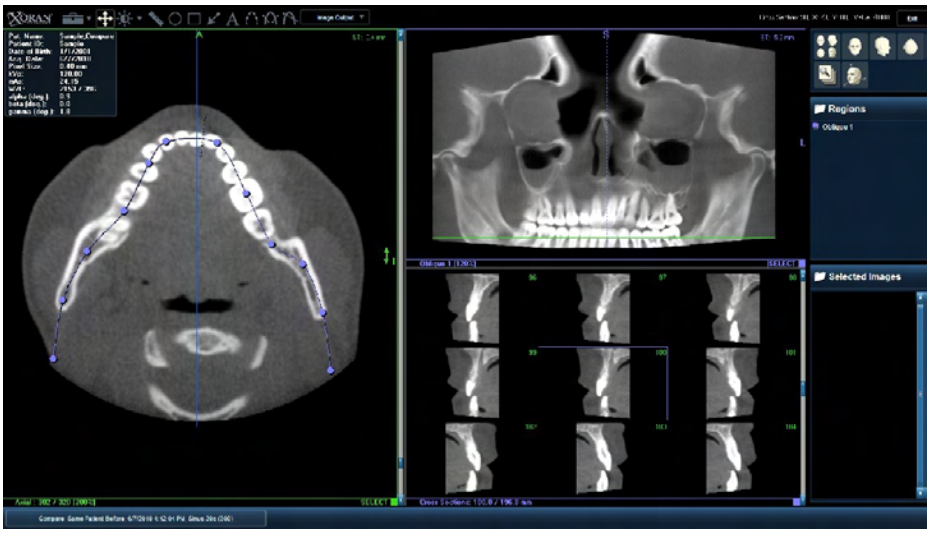

- A new entry appears in the Regions menu as "Oblique 1". You can toggle between this view and others by selecting the desired view in the navigation menu (top right corner), or clicking on the view in the Regions menu.
- The image on the left side shows the oblique pathway.
- The image at the top right shows the cut along the oblique pathway.
- The slice thickness is 0.4 mm and can be changed by left-clicking on the Slice Thickness (ST) value in the top right corner of the image and selecting a new value.
- The thumbnail images in the bottom right frame are cuts that are perpendicular to the oblique pathway. These are equally spaced along the length of the oblique pathway.
- The highlighted thumbnail image indicates the location within the oblique pathway, as represented by the perforated line on the left image and the top right image.

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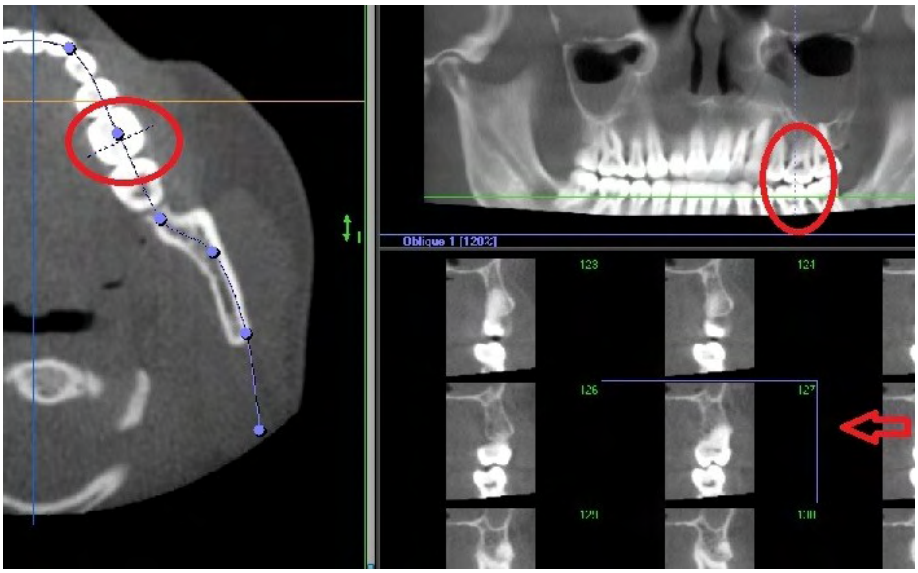
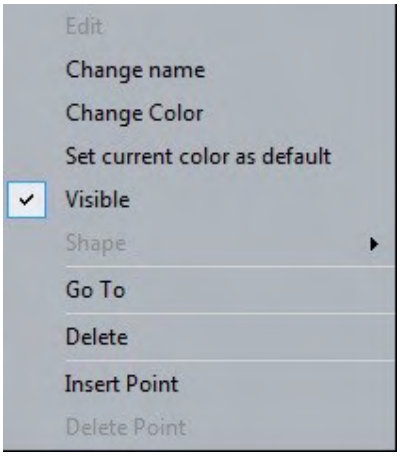


- Move the oblique line by hovering over it with the cursor until it is active (it will change color), grabbing it by holding down the left mouse button and dragging it to the desired location.

- Make changes to the oblique line by moving the cursor over it until the oblique line changes color and then right-clicking the mouse. A drop-down menu will appear with options. Make similar changes by right-clicking the corresponding oblique line in the Navigation menu and choosing from the menu options.



Oblique Options	Description
Change Name	Changes the name of the object.

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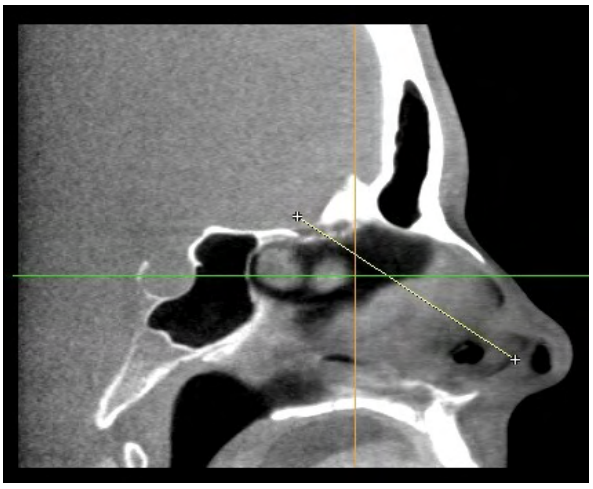
Oblique Options	Description
Change Color	Changes the color.
Set current color as default	Sets the current color of the oblique object as the default color for subsequent oblique objects.
Visible	De-selecting this option makes the line disappear from view. Bring the object back to view by right-clicking the corresponding object from the *Regions* menu and selecting **Visible.**
Go To	Opens the *Oblique* window (the new screen that appears after you define an oblique line).
Delete	Deletes the oblique line.
Insert Point	Inserts an additional point to the oblique object.
Delete Point	Deletes the selected point from the oblique object.

Two Points Oblique Tool

1. Click on the **Two Points Oblique** icon . When this icon is active, you have the ability to flatten oblique and curved objects into a two-dimensional view.
2. Left-click to deposit two points along the desired pathway. An example is shown below (a yellow line with cross hairs representing the click points).



3. The following window will appear:

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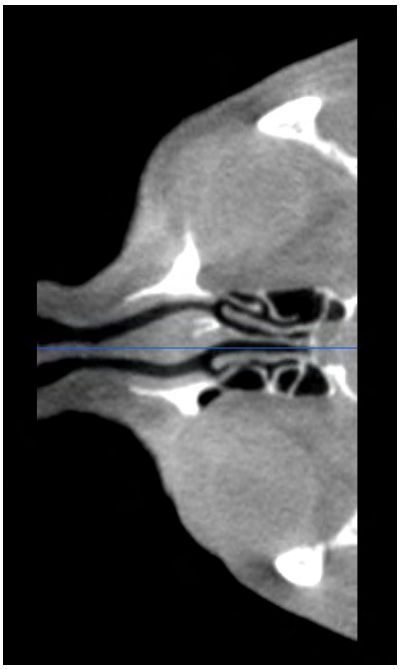

- A new entry appears in the navigation menu as 'Two Points Oblique 1". You can toggle between this view and others by selecting the desired view in the navigation menu (top right corner), or clicking on the view in the Regions menu.
- The image on the left side shows the oblique pathway.
- The image on the lower right shows the cut along the oblique pathway.
- The slice thickness is 0.4 mm and can be changed by left-clicking on the Slice Thickness (ST) value in the top right corner of the image and selecting a new value.
- Move the oblique line by hovering over it with the cursor until it is active (it will change color), grabbing it by holding down the left mouse button, and dragging it to the desired location.
- Make changes to the oblique line by moving the cursor over it until the oblique line changes color and then right-clicking the mouse. A drop-down menu will appear with options. Make similar changes by right-clicking the corresponding oblique line in the Navigation menu and choosing from the menu options.

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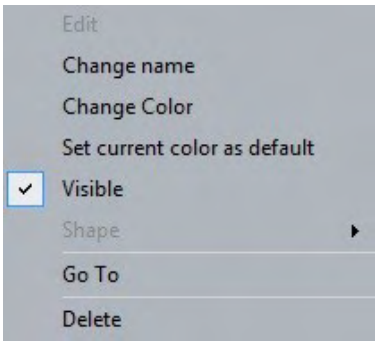

Two Points Oblique Options	Description
Change Name	Changes the name of the object.
Change Color	Changes the oblique line color.
Set current color as default	Sets the current color of the Two Points Oblique object as the default color for subsequent Two Points Oblique objects.
Visible	De-selecting this option makes the line disappear from view. Bring the object back to view by right-clicking the corresponding object from the *Regions* menu and selecting **Visible.**
Go To	Takes you to the *Oblique* window (the screen that appears after you define an oblique line).
Delete	Deletes the oblique line.

TMJ Tool

The TMJ (Temporomandibular Joint) tool can be used in the Axial plane.

1. Click on the **TMJ** icon . When this icon is active, you have the ability to look at the temporal mandibular joints in a two-dimensional view.
2. Left-click below and to the right of the patient's left condyle (this is a radiological view, so patient's left is the right side of the image). Alternatively, you could choose a point below and to the left of the patient's right condyle. The point chosen for this example is highlighted with the red arrow.

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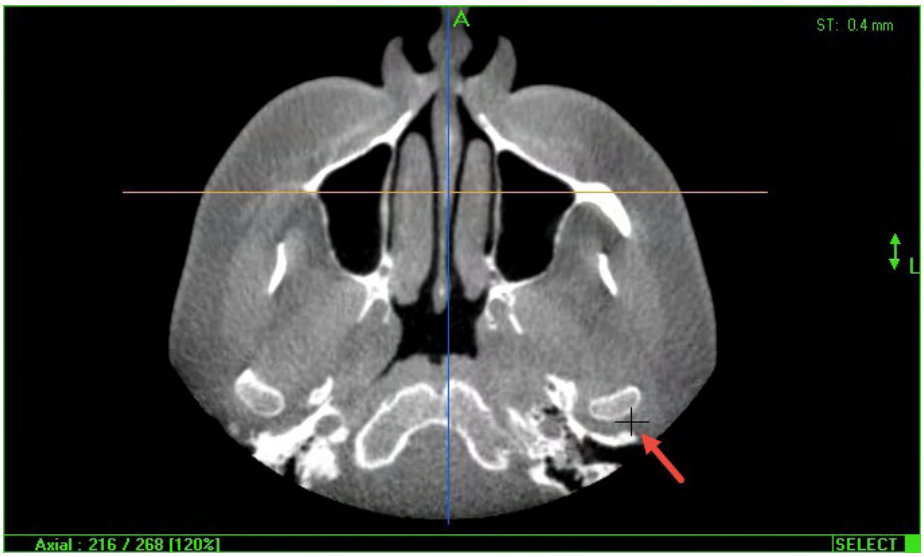
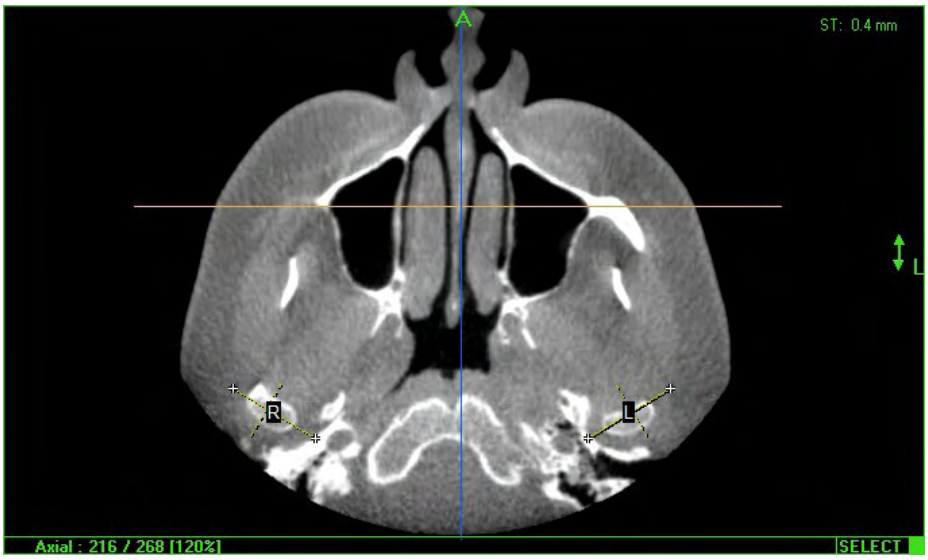


3. Move the cursor up and to the right (patient's left) to deposit the second point. The line that connects these two points should cross over the center of the joint. The second point chosen for this example is highlighted with the red arrow.

As soon as this point is selected, the letter "L" appears over this line, indicating the patient's left. A second line appears on the patient's right side that may or may not be over the right condyle. You can move this line so that it is positioned properly.



4. The following screen will appear:

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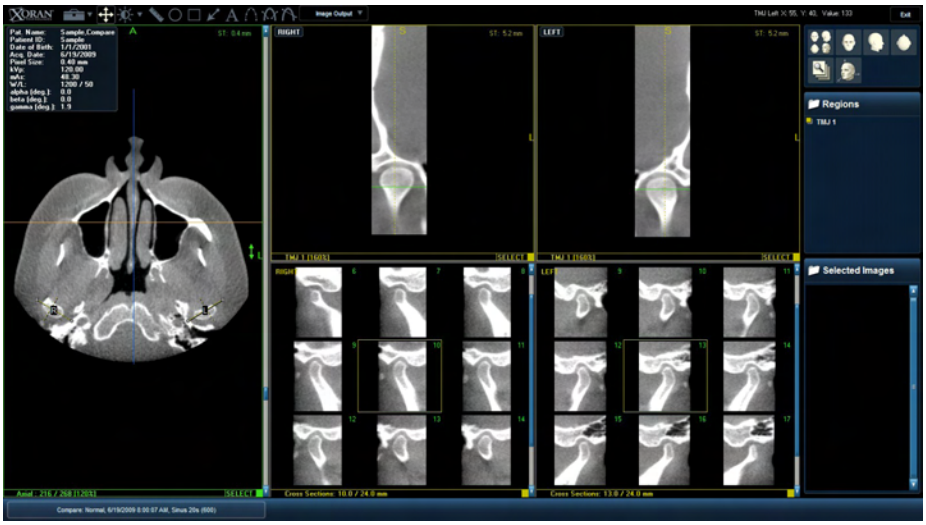

- A new entry appears in the Navigation menu as 'TMJ 1". You can toggle between this view and others by selecting the desired view in the navigation menu (top right corner), or clicking on the view in the Regions menu.

- The two images in the upper right portion of the screen are the right and left image cuts along the TMJ lines.

- The default slice thickness is 5.2 mm and can be changed by left-clicking on the Slice Thickness (ST) value in the top right corner of each image and selecting a new value.

- The two panes of small images are cuts that are perpendicular to the TMJ lines. These are equally spaced along the length of each TMJ line.

- Move the TMJ lines by hovering over them with the cursor until they are active (they will change color), grabbing them by holding down the left mouse button, and dragging them to the desired location.

- Make changes to the TMJ lines by moving the cursor over them until the TMJ lines change color and then right-clicking with the mouse. A drop-down menu will appear with options. Make similar changes by right-clicking the corresponding TMJ lines in the Navigation menu and choosing from the following menu options:

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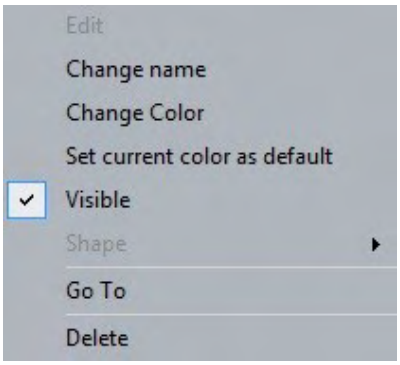

TMJ Options	Description
Change Name	Changes the name of the TMJ object.
Change Color	Changes the TMJ line color.
Set current color as default	Sets the current color of the TMJ object as the default color for subsequent TMJ objects.
Visible	De-selecting this option makes the line disappear from view. Bring the object back to view by right-clicking the corresponding object from the *Regions* menu and selecting **Visible**.
Go To	Takes you to the *TMJ* window (the screen that appears after you define a pair of TMJ lines).
Delete	Deletes the pair of TMJ lines.

7.7 3D Viewing Window

To enable the 3D viewing window, click the Tools menu from the Patient Database and select Show 3D.

To reconstruct the 3D window after an acquisition, click Show in the bottom-right corner of the 3D plane in the MPR window.

Zoom

1. Select the Pan/Zoom tool from the toolbar.

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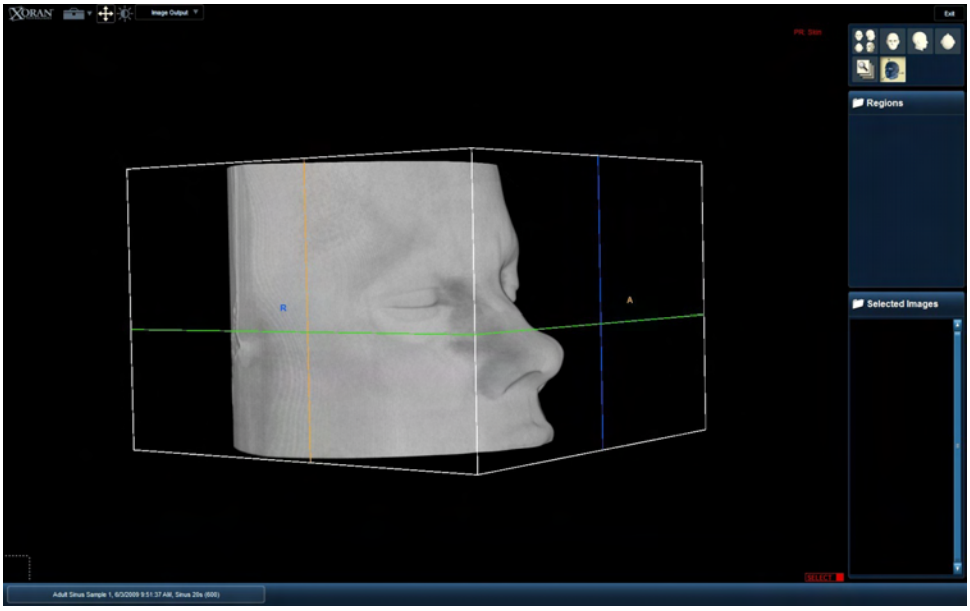
2. Place the cursor anywhere in the image (except over the colored lines).

    - Left-click to zoom in.
    - Right-click to zoom out.



Rotate

1. Click and hold anywhere on the screen.

    - Drag the cursor in the direction you want to rotate the view.

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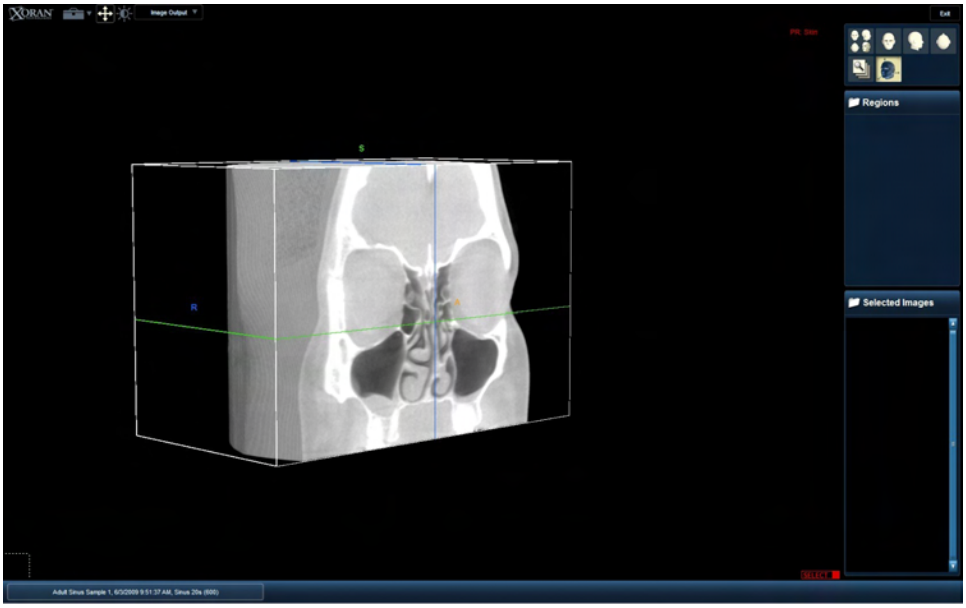
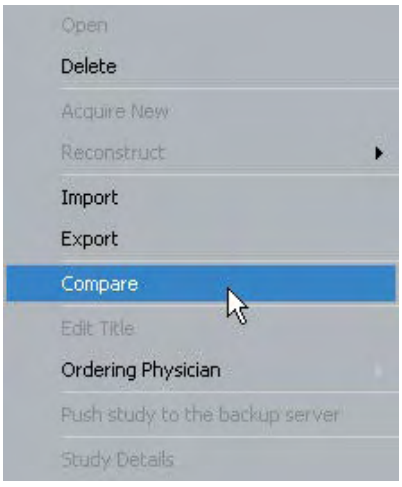
Cross-sectional Views

1. Click the edge of one of the planes and move it towards the other parallel plane.



7.8 Comparison Tool

1. To enable the comparison tool, select any two reconstructed studies.
    - To select multiple studies, click on two studies while holding Ctrl.
2. Right-click and select **Compare**.



- When reconstructed studies from different patients are compared, a confirmation window will appear asking to proceed.

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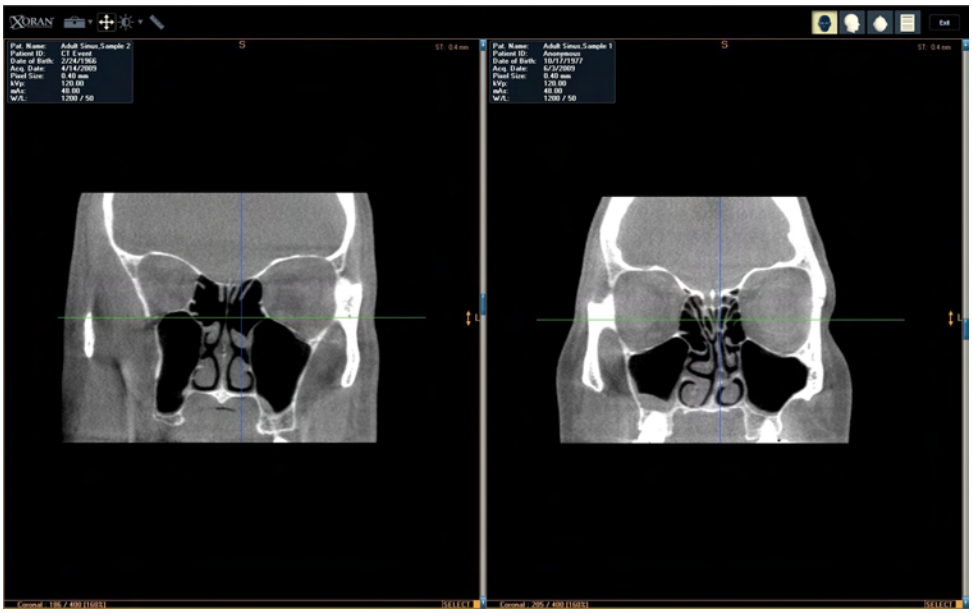
3. Side-by-side single-planar views will appear. You can switch between the coronal view (shown below), sagittal, and axial.



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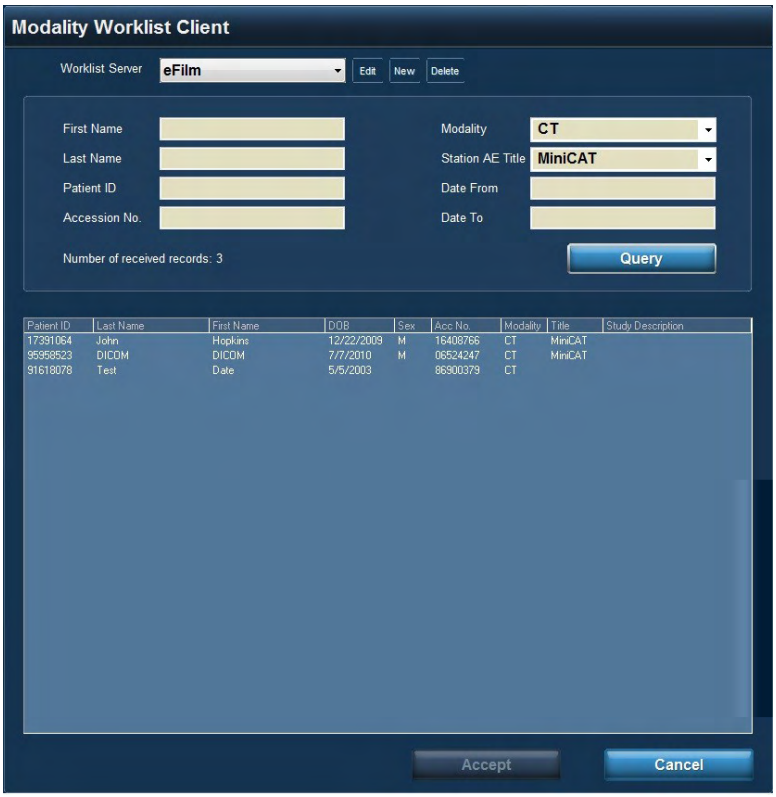
8.0 MODALITY WORKLIST CLIENT

The Modality Worklist Client software allows patient demographic information to be electronically transmitted to the MiniCAT™ scanner so that the operator does not need to enter the data manually. The imaging order is placed electronically (by an external information system) and a DICOM file is generated containing patient demographic information which is sent to the MiniCAT™. The scanner operator simply selects the patient name from a list of scans that have been ordered and performs the scan. The scan image data is attached to the demographic data and sent out to the facility PACS system. An active internet connection is required to use the Modality Worklist Client.

Query

A **Query** searches the hospital database for user-defined information.

1. Select a Worklist Server from the drop-down menu.
2. Enter as much patient-specific data as possible in the appropriate fields.
3. Click **Query**.



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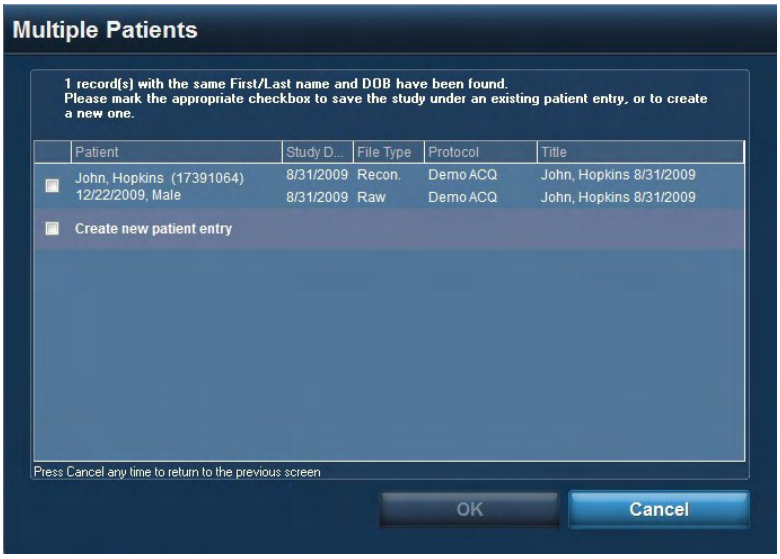
4. Select a record to accept into the Patient Database. Click **Accept**. All applicable data is automatically imported from the server into the Patient Database.

When a patient record in the server is similar (i.e. two records have the same patient name and same birthdate) to a patient record already in the Patient Database, you can either merge the records by checking the box next to the patient name, or create a new record if they are different patients.


Multiple Patients
1 record(s) with the same First/Last name and DOB have been found.
Please mark the appropriate checkbox to save the study under an existing patient entry, or to create a new one.
Patient
Study D...
File Type
Protocol
Title
John, Hopkins (17391064) 12/22/2009, Male
8/31/2009 Recon.
Demo ACQ
John, Hopkins 8/31/2009
8/31/2009 Raw
Demo ACQ
John, Hopkins 8/31/2009
Create new patient entry
Press Cancel any time to return to the previous screen
OK
Cancel

If you choose to merge the records, inconsistent data will be highlighted in red. Click **Yes** to merge the data.

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9.0 OUTPUT IMAGES

The MiniCAT™ makes image output easy with preset protocols for printing, burning to CD/USB drive and transferring images over a network.

1. If printing, ensure that the desired slices appear under **Selected Slices** view.
2. Click the **Image Output** menu (along the main toolbar of the screen) to view all output protocols.

3. Left-click on the desired image output protocol. A sample list of Output Protocols are shown below. For additional protocols, please contact Xoran Customer Service.

Output Protocol	Description
Print Selected Images	Automatically prints the images in the *Selected Images* window. The default image layout is 3 rows by 2 columns.
Export Xoran Study	Exports Xoran study data to either a CD or USB flash drive.
Burn DICOM CD	Burns a Xoran image data onto a CD in DICOM format, which is compatible with most IGS systems.
Export to HTML	Exports a Xoran study in HTML format, viewable on any computer with a browser such as Internet Explorer.
Export to DICOM Axial	Exports the axial slices of a Xoran study onto a CD in DICOM format.
Export to JPEG	Exports a Xoran study in JPEG picture format.
DICOM Push	Allows a study to be uploaded to a DICOM server such as a PACS system. Call Xoran Customer Service to help set this up.

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10.0 TECHNICAL SPECIFICATIONS

10.1 General Information

MiniCAT™ Scanner

System Description	MiniCAT™ is a compact, upright, volume computed tomography (VCT) imaging system designed for high-resolution, low-radiation imaging of the sinuses, skull base and temporal bones.
System Dimensions	40" L x 36" W x 67" H (102 cm x 91 cm x 170 cm)
Weight	450 lbs

Patient Support

Overall Dimensions	28" L x 18" W x 50" H (71 cm x 46 cm x 127 cm)
Weight	115 lbs (52 kg)
Seat Height Adjustment	15.5" to 42" (39 cm to 107 cm)
Maximum Patient Weight	350 lbs (159 kg)

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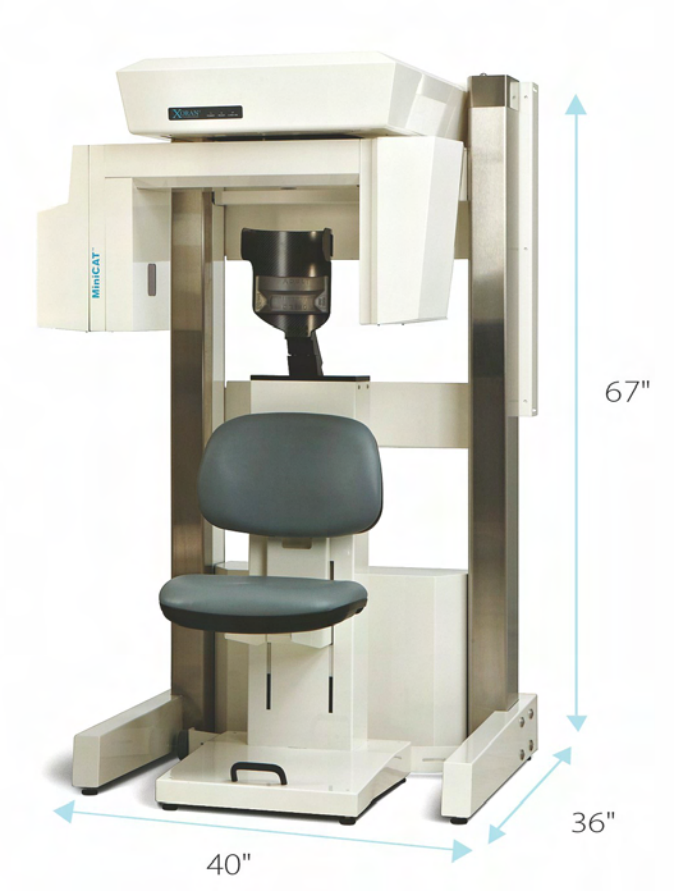
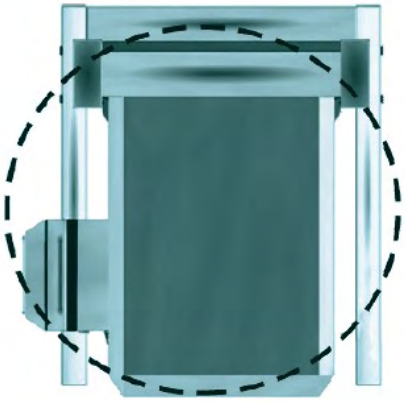
FRONT VIEW



TOP VIEW



46” Gantry Rotation Diameter

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10.2 Imaging Properties

Imaging Properties	
Slice Thickness	0.3 mm minimum for Temporal Bone (reconstructed) 0.4 mm minimum for Sinus (reconstructed)
Reconstruction Time	<30 s for 600 frames
Sinus Field of View, Axial	10.5 cm
Sinus Field of View, Cross-sectional	16.0 cm
Temporal Bone Field of View, Axial	6.0 cm
Temporal Bone Field of View, Cross-sectional	16.0 cm
Number of Slices in a typical sinus scan	approximately 270 Axial slices
Number of Data Channels Used	744 (Sinus scans) 412 (Temporal bone scan)
Views	MPR/Axial/Coronal/Sagittal/Oblique/3D/TMJ/ Side-by-Side
Gray Scale Display	256 levels
Display Window	Adjustable level and width
Compatibility	DICOM 3.0

Acquisition Protocols (SourceRay Source)							
	Tube Voltage	**Tube Current**	**Pulse Length**	**Number of Frames**	**Exposure**	**Scan Time**	**Default Reconstruction Protocol**
Sinus 20s (600)	120 kVp	7 mA	11.5 ms	600	48.30 mAs	20 s	SMOOTH (400x400 0.4, 0.4, f1)
Sinus 10s (300)	120 kVp	7 mA	11.5 ms	300	24.15 mAs	10 s	SMOOTH (400x400 0.4, 0.4, f1)
Sinus 10s (150)	120 kVp	7 mA	11.5 ms	150	12.08 mAs	10 s	SMOOTH (400x400 0.4, 0.4, f1)

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T Bone 20s (600)	125 kVp	7 mA	14 ms	600	58.80 mAs	20 s	SHARP (536x536 0.3, 0.3, f0)
Resolution Calibration	120 kVp	7 mA	11.5 ms	600	48.30 mAs	40 s	SHARP (800x800 0.2, 0.2, f0)
Water Calibration	120 kVp	7 mA	11.5 ms	600	48.30 mAs	40 s	SMOOTH (400x400 0.4, 0.4, f1)
Legacy Acquisition Protocols (ISI Source)							
Sinus 40s (600)	120 kVp	5 mA	16 ms	600	48 mAs	40 s	SMOOTH (400x400 0.4, 0.4, f1)
Sinus 20s (300)	120 kVp	5 mA	16 ms	300	24 mAs	20 s	SMOOTH (400x400 0.4, 0.4, f1)
Sinus 10s (150)	120 kVp	5 mA	16 ms	150	12 mAs	10 s	SMOOTH (400x400 0.4, 0.4, f1)
T Bone 40s (600)	125 kVp	7 mA	18 ms	600	75.6 mAs	40 s	SHARP (536x536 0.3, 0.3, f0)
Resolution Calibration	125 kVp	7 mA	18 ms	600	75.6 mAs	40 s	SHARP (800x800 0.2, 0.2, f0)
Water Calibration	120 kVp	5 mA	16 ms	600	48 mAs	40 s	SMOOTH (400x400 0.4, 0.4, f1)
Legacy Acquisition Protocols (SourceRay Source)							
Sinus 40s (600)	120 kVp	7 mA	11.5 ms	600	48.30 mAs	40 s	SMOOTH (400x400 0.4, 0.4, f1)
Sinus 20s (300)	120 kVp	7 mA	11.5 ms	300	24.15 mAs	20 s	SMOOTH (400x400 0.4, 0.4, f1)
Sinus 10s (150)	120 kVp	7 mA	11.5 ms	150	12.08 mAs	10 s	SMOOTH (400x400 0.4, 0.4, f1)
T Bone 40s (600)	125 kVp	7 mA	14 ms	600	58.80 mAs	40 s	SHARP (536x536 0.3, 0.3, f0)
Resolution Calibration	125 kVp	7 mA	14 ms	600	58.80 mAs	40 s	SHARP (800x800 0.2, 0.2, f0)
Water Calibration	120 kVp	7 mA	11.5 ms	600	48.30 mAs	40 s	SMOOTH (400x400 0.4, 0.4, f1)

Note: If you are using legacy acquisition protocols and are unsure which source you have, please contact Xoran Customer Service.

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Reconstruction Protocols					
	Coronal Slices	**Sagittal Slices**	**Voxel Width/ Depth**	**Voxel Height**	**Filter Type**
SMOOTH (400x400 0.4, 0.4, f1)	400	400	0.4	0.4	Hann
SHARP (536x536 0.3, 0.3, f0)	536	536	0.3	0.3	Ramp
SHARP (800x800 0.2, 0.2, f0)	800	800	0.2	0.2	Ramp

Filter Type	
	Description
Ramp	Provides sharp image detail with high-contrast resolution.
Hann	Provides smooth image detail with low noise.

MiniCAT Scan Parameters	
Maximum number of slices per acquisition	Cone Beam CT
Acquisition series	Volume
Reformat technique	Multi-planar reconstruction
kVp/mAs	600 Frame Sinus: 120 kVp / 48 mAs 300 Frame Sinus: 120 kVp / 24 mAs 150 Frame Sinus: 120 kVp / 12 mAs T Bone 20s (600): 125 kVp / 58 mAs T Bone 40s (600) (ISI): 125 kVp / 76 mAs T Bone 40s (600) (SourceRay) 125 kVp / 58 mAs
Dose length product	Sinus 20s (600): 97.0 mGy-cm Sinus 10s (300): 49.2 mGy-cm Sinus 10s (150): 24.6 mGy-cm T Bone 20s (600): 76.9 mGy-cm ISI Source Sinus 40s (600): 85.2 mGy-cm Sinus 20s (300): 42.5 mGy-cm

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	Sinus 10s (150): 20.6 mGy-cm T Bone 40s (600): 62.8 mGy-cm SourceRay Source Sinus 40s (600): 97.0 mGy-cm Sinus 20s (300): 49.2 mGy-cm Sinus 10s (150): 24.6 mGy-cm T Bone 40s (600): 76.9 mGy-cm
Tube current modulation or dose reduction technique	Pulsed Beam, Limited mA, Collimation
Total effective dose estimate per acquisition	Sinus 20s (600): 0.17 mSv Sinus 10s (300): 0.09 mSv Sinus 10s (150: 0.04 mSv T Bone 20s (600): 0.14 mSv
Prescribed rotation time	Sinus 20s (600): 20 seconds Sinus 10s (300): 10 seconds Sinus 10s (150): 10 seconds T Bone 20s (600): 20 seconds Sinus 40s (600): 40 seconds Sinus 20s (300): 20 seconds Sinus 10s (150): 10 seconds T Bone 40s (600): 40 seconds
Increment	N/A
Detector collimation (mm)	Sinus: 189 mm Temporal Bone: 105 mm
Slice thickness	Sinus: Selectable (0.4 mm minimum reconstructed) Temporal Bone: Selectable (0.3 mm minimum reconstructed)
Pitch or table feed	N/A
Scan FOV	Sinus: 16 x 10.5 cm Temporal Bone: 16 x 6 cm
Gantry tilt/angle	N/A
Kernel/filter	Sinus: Hann Temporal Bone: Ramp

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Geometry	
Image Receptor Dimensions	Active area 241.3 x 192.5 mm
Source-to-Image Receptor Distance (CF Cover)	685.86 ± 1.37 mm
Source-to-Image Receptor Distance (Active Area)	700.86 ± 1.40 mm
Source-to-Isocenter Distance	480.34 ± 0.96 mm
Central Slice Location	Central Slice Laser ± 5 mm
Primary Beam Dimension at Isocenter for Sinus scans	167.2 ± 2.5 x 129.5 ± 1.9 mm
Superior of central slice	32.7 ± 1.6 mm
Inferior of central slice	96.8 ± 4.8 mm
Primary Beam Dimension at Isocenter for Temporal Bone scan	167.2 ± 2.5 x 71.9 ± 1.1 mm
Superior of central slice	32.8 ± 1.6 mm
Inferior of central slice	39.1 ± 1.9 mm
Number of detector elements	1536 x 1920
Element Spacing (dimensions)	0.127 x 0.127 mm

Image Noise

The following table gives the noise for each imaging protocol with maximum deviations.

Protocol Name(s)	Noise Level (% of water attenuation)	
Sinus 20s (600), Sinus 40s (600)	2.88 ± 1.00	
Sinus 10s (300), Sinus 20s (300)	4.86 ± 2.18	
Sinus 10s (150)	7.09 ± 2.60	
T Bone 20s (600), T Bone 40s (600)	5.72 ± 2.19	

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Tomographic Section Thickness

The following table gives the tomographic section thickness for each imaging protocol with maximum deviations.

Protocol Name(s)	Tomographic Section Thickness (mm)	
Sinus 20s (600), Sinus 40s (600)	0.542 ± 0.048	
Sinus 10s (300), Sinus 20s (300)	0.547 ± 0.071	
Sinus 10s (150)	0.536 ± 0.130	
T Bone 20s (600), T Bone 40s (600)	0.532 ± 0.043	

Measuring Nominal Tomographic Section Thickness is obtained by finding the full-width half-maximum (FWHM) resolution of the Slice Sensitivity Profile (SSP). The SSP is obtained by scanning a small, sub-voxel bead in the QC module. However, the nominal tomographic section thickness is fixed for each protocol and is not selectable prior to acquisition.

Slice Sensitivity Profiles

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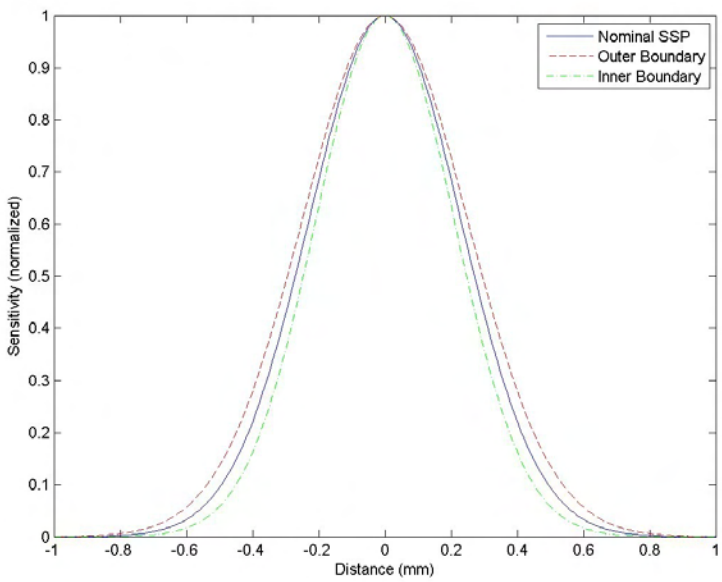
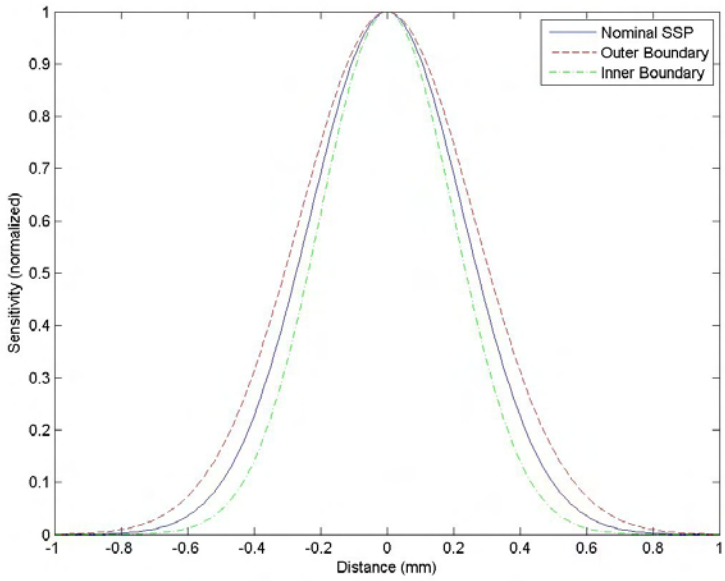
Sinus 20s (600), Sinus 40s (600)



Sinus 10s (300), Sinus 20s (300)



Sinus 10s (150)

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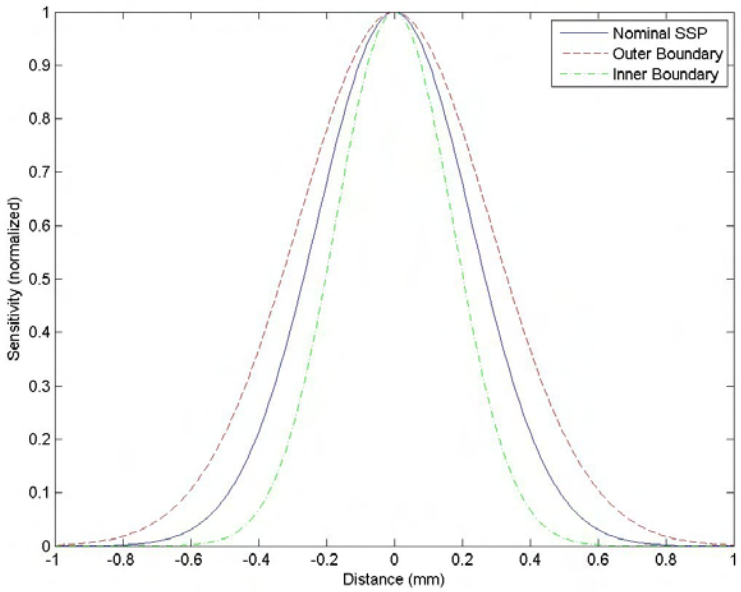
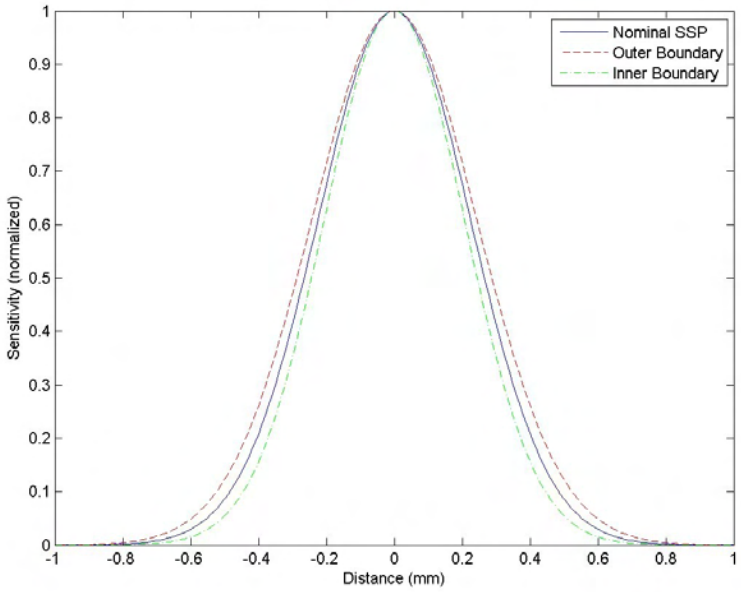


T Bone 20s (600), T Bone 40s (600)



MTF Profiles

The Modulation Transfer Function (MTF) is the amplitude frequency response of the imaging protocol and is a commonly used measure of system blur. The MTF profiles are given in the figures

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below.

Maximum Deviation: The spatial frequency corresponding to the 50% and 10% contrast levels in the MTF graphs will have the guaranteed lower bounds listed in the table below.

Lower bounds on 50% and 10% contrast cut-off frequencies for MTFs of different protocols in units of oscillations per centimeter		
Protocol	**50% Contrast**	**10% Contrast**
Sinus 20s (600), Sinus 40s (600)	3.33	6.00
Sinus 10s (300), Sinus 20s (300)	3.33	6.00
Sinus 10s (150)	3.33	6.00
T Bone 20s (600), T Bone 40s (600)	5.00	10.00

Apparatus

The apparatus for MTF measurement consists of an acrylic cylinder phantom, 10 cm in diameter and 2.5 cm long axially, embedded with a tungsten wire filament. The tungsten wire filament is 50 microns in diameter.

Data Acquisition Methodology

An acquisition and reconstruction of the phantom is made in the desired imaging mode, with the tungsten filament centered horizontally in the field of view and vertically about the equatorial plane of the scanner (the plane of rotation of the focal spot). The vertical axis of the phantom should be aligned as closely as possible with the z-axis of the scanner. *Note that, the vertical axis of the phantom is NOT the axis parallel to the wire filament. Rather it is the axis around which the acrylic casing of the wire is circularly symmetric.* The phantom was positioned to maximize the view of the axial length of the phantom. More viewable slices translate into more data for estimation and improved MTF estimation accuracy.

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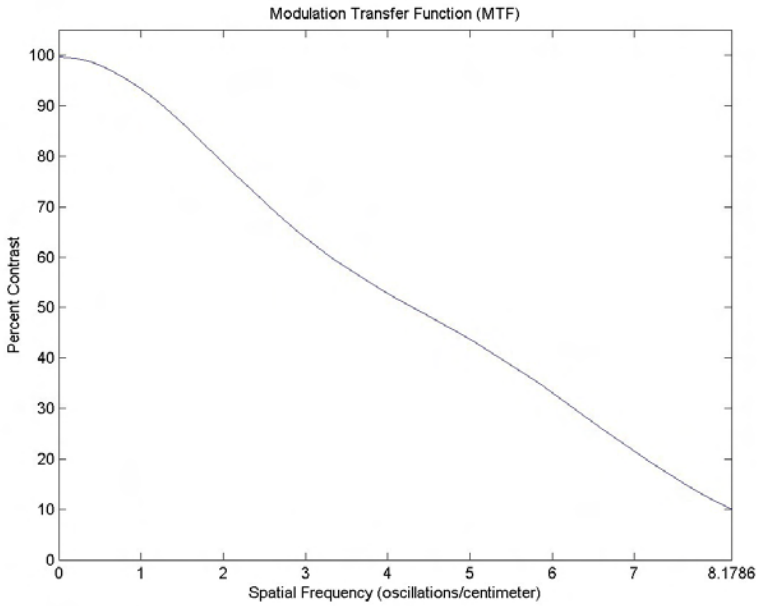
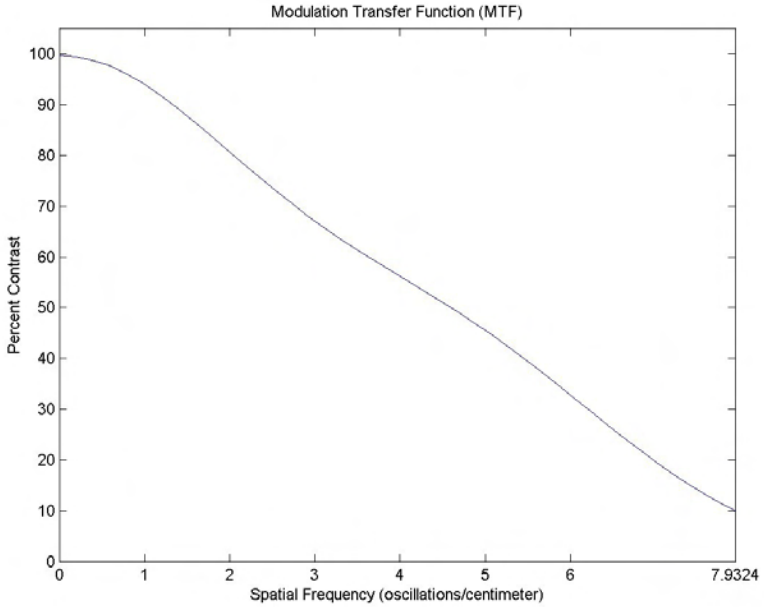
Sinus 20s (600), Sinus 40s (600)



Sinus 10s (300), Sinus 20s (300)



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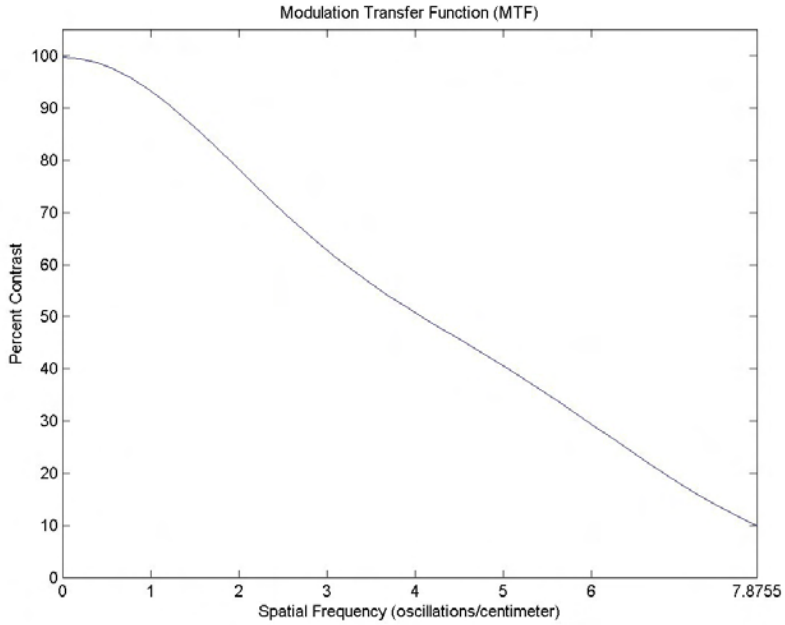
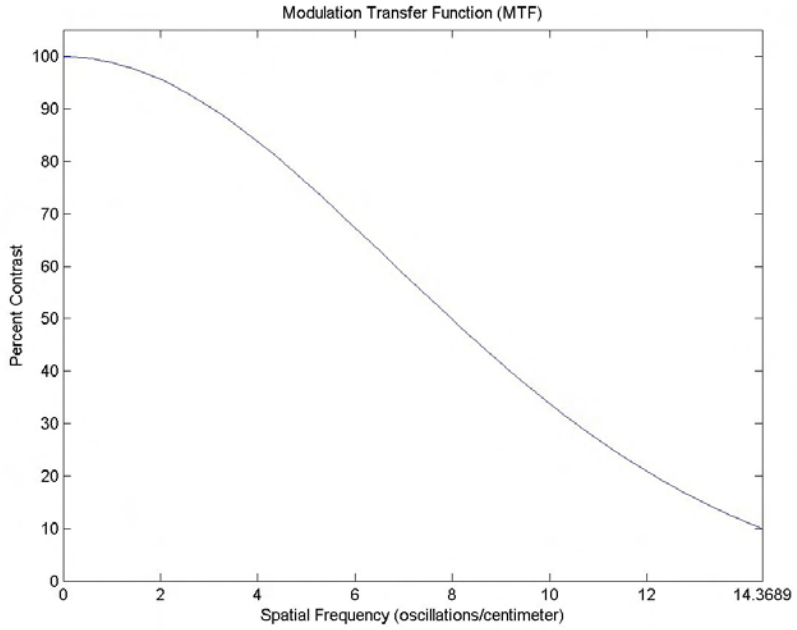
Sinus 10s (150)



T Bone 20s (600), T Bone 40s (600)



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10.3 X-Ray Specifications

X-Ray Specifications	
Source Block Manufacturers	Source-Ray, Inc., Imaging Sciences International, Inc. (ISI)
Source Block Model	SB-125-7K
Tube Manufacturer	Superior X-Ray Tube Co.
Tube Model Number	SXR-130-15-0.5
Tube Type	Stationary anode
Nominal Tube Potential Range	120 - 125 kVp ±5% tolerance
Nominal Tube Current Range r.m.s.	5 - 7 mA ±5% tolerance
Max. Tube Voltage	130 kVp (full wave rectified)
Max. Tube Current r.m.s.	8 mA
Target Material	Tungsten
Target Angle	15 degrees
Focal Spot Size	~0.5 mm (NEMA)
Minimum Inherent Filtration	2.0 mm Al @ 125 kVp
Rated Line Voltage	~120V AC, 50/60 Hz, 10A (r.m.s max line current) (integrated into diagnostic system)
Range of Line Voltage Regulation	2%
Maximum line current r.m.s	10A
Technique Factors that Constitute the Maximum Line Current Condition	125 kVp, 58.8 mAs
X-ray Generator Duty Cycle	Pulsed: 50% duty cycle, 11-30 ms pulse on time Pulse Train: 30 pulses/sec (Hz) Pulse Train Time: 40 seconds on, 10 minutes off
Rise Time (X-Ray Output)	Less than 5 ms @ 125 kVp 7 mA measured @ 50% - 90 % of the voltage waveform.

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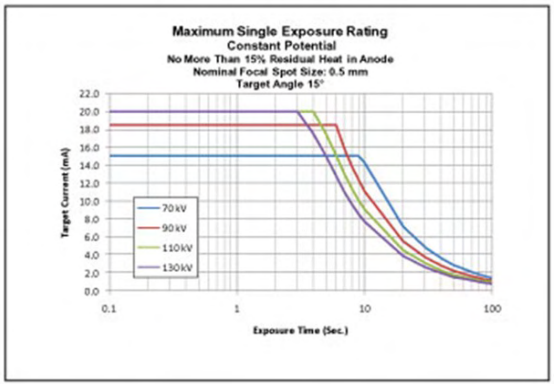
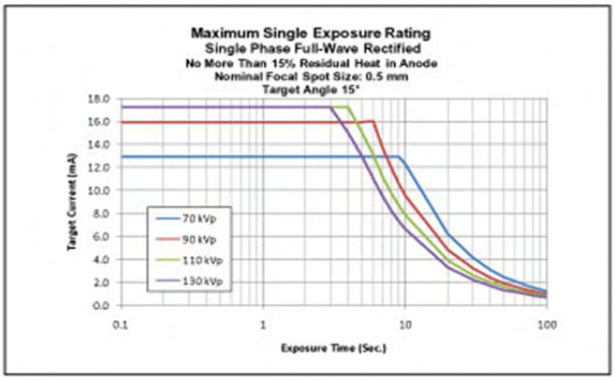
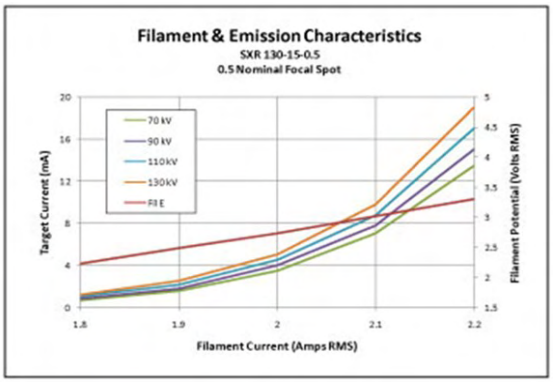
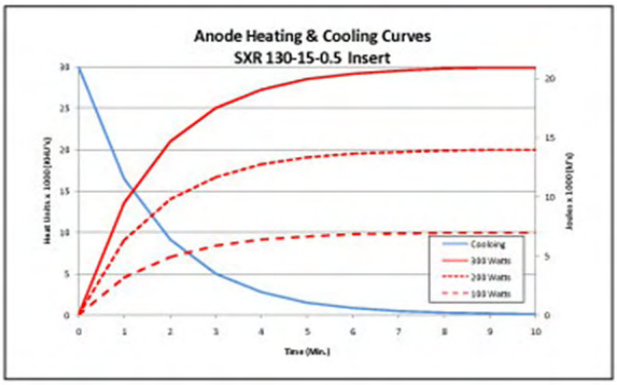
Leakage Radiation	Less than 100 mR/Hr
Leakage Technique Factors (SourceRay Source)	125 kV, 7 mA, 0.014 s pulse width, 30Hz, 8% duty cycle
Leakage Technique Factors (ISI Source)	125 kV, 7 mA, 0.018 s pulse width, 15Hz, 16% duty cycle
Beam Quality - half-value layer (HVL) (SourceRay Source)	9.4 mm equivalent Al @ 120 kVp 9.7 mm equivalent Al @ 125 kVp
Beam Quality - half-value layer (HVL) (ISI Source)	10.6 mm equivalent Al @ 120 kVp 10.9 mm equivalent Al @ 125 kVp
Minimum Permanent Filtration (SourceRay Source)	11.7 mm Al equivalent
Minimum Permanent Filtration (ISI Source)	10.6 mm Al equivalent
Measurement Criteria for Peak Voltage, Current, and Pulse Width	50% - 90 % of the voltage waveform, 125 kVp, 58.8 mAs









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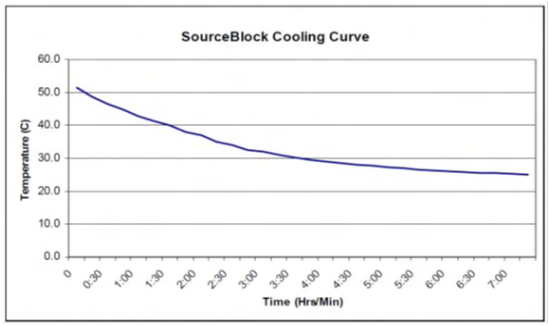

10.4 Scatter Map

Secondary Radiation Measurements

Secondary scatter radiation was measured on the MiniCAT™ at 6 azimuthal locations A through F and at radii 1.0, 1.5, and 2.0 meters from isocenter and in the same plane as the central slice (i.e. level with the focal spot) which was approximately 120 centimeters above the floor (see diagram below).

The MiniCAT™ was operated at 120 kVp and 48.3 mAs per Sinus 20s (600) protocol for all secondary radiation measurements reported.

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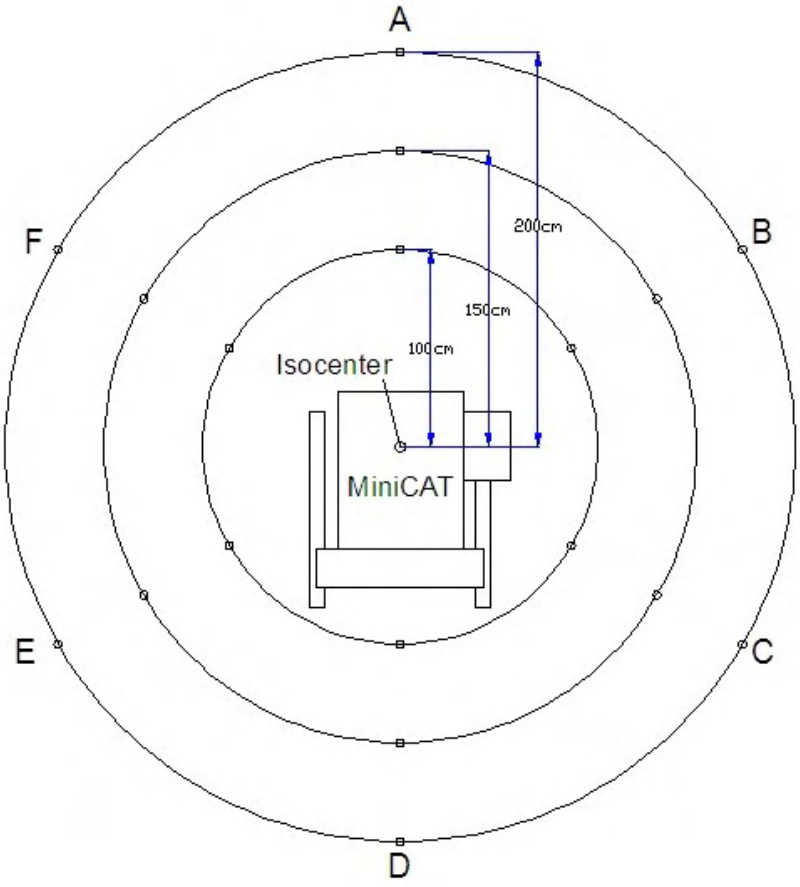

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Secondary Dose Measurements Per Scan Level with Central Slice		
Azimuthal Location	**Radius (meter)**	**Dose Per Scan (millirad)**
A	1.0	0.877
	1.5	0.438
	2.0	0.257
B	1.0	0.919
	1.5	0.420
	2.0	0.261
C	1.0	1.050
	1.5	0.438
	2.0	0.257
D	1.0	1.101
	1.5	0.438
	2.0	0.271
E	1.0	1.092
	1.5	0.480
	2.0	0.271
F	1.0	0.812
	1.5	0.373
	2.0	0.261

The secondary radiation doses were also recorded at 0.5 meters above and 0.5 meters below the horizontal plane intersection the central slice at azimuthal locations A through F and at a radius of 1.0 meter. These measurements are reported in the following tables.

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Secondary dose measurements per scan 0.5 meters below central slice at radius of 1 meter	
Azimuthal Location	**Dose Per Scan (millirad)**
A	1.07
B	0.93
C	0.98
D	0.84
E	0.91
F	0.94

Secondary dose measurements per scan 0.5 meters above central slice at radius of 1 meter	
Azimuthal Location	**Dose Per Scan (millirad)**
A	0.60
B	0.70
C	0.76
D	0.02
E	0.78
F	1.76

10.5 Dose Information

SourceRay Source

The CT conditions of operation used to provide dose and imaging performance information below are as follows:

Sinus 20s (600): 120 kVp, 7 mA, 11.5 ms pulses, 600 pulses (48.3 mAs), 11.7 mm Al equivalent fixed filtration, 0.542 ± 0.048 mm tomographic section thickness.

Sinus 10s (300): 120 kVp, 7 mA, 11.5 ms pulses, 300 pulses (24.15 mAs), 11.7 mm Al equivalent

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fixed filtration, 0.547 ± 0.071 mm tomographic section thickness.

Sinus 10s (150): 120 kVp, 7 mA, 11.5 ms pulses, 150 pulses (12.08 mAs), 11.7 mm Al equivalent fixed filtration, 0.536 ± 0.130 mm tomographic section thickness.

T Bone 20s (600): 125 kVp, 7 mA, 14.0 ms pulses, 600 pulses (58.8 mAs), 11.7 mm Al equivalent fixed filtration, 0.532 ± 0.043 mm tomographic section thickness.

The nominal tomographic section thickness is fixed for each protocol and is not selectable prior to acquisition.

Dose Measurements - SourceRay Source

Protocol	$CTDI_{VOL}$ (mGy)	DLP (mGy-cm)
Sinus 20s (600) Sinus 40s (600)	5.1	97.0
Sinus 10s (300) Sinus 20s (300)	2.6	49.2
Sinus 10s (150)	1.3	24.6
T Bone 20s (600) T Bone 40s (600)	7.3	76.9

21CFR1020.33 Subsection	Description	Protocol (SourceRay Source)	Result
(c)(2)(i)(a)	CTDI at center for typical factors	Sinus 20s (600) Sinus 40s (600)	5.4 mGy
	CTDI at center for typical factors	T Bone 20s (600)	7.7 mGy

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		T Bone 40s (600)	
(c)(2)(i)(b)	CTDI at max periphery. The location of maximum exposure for the Sinus protocol was found to be at approximately the 8 o'clock position when facing the MiniCAT and looking down on the CTDI phantom.	Sinus 20s (600) Sinus 40s (600)	5.0 mGy
	CTDI at max periphery. The location of maximum exposure for the Temporal Bone protocol was found to be at approximately the 2 o'clock position when facing the MiniCAT and looking down on the CTDI phantom.	T Bone 20s (600) T Bone 40s (600)	7.1 mGy
(c)(2)(i)(c)	CTDI for locations at 90, 180, and 270 degrees from the position of maximum at periphery, respectively.	Sinus 20s (600) Sinus 40s (600)	5.0, 4.8, and 4.7 mGy
	CTDI for locations at 90, 180, and 270 degrees from the position of maximum at periphery, respectively.	T Bone 20s (600) T Bone 40s (600)	6.8, 6.9, and 7.0 mGy
(c)(2)(i)(c)(ii)	For each selectable protocol that varies the duration of x-ray exposure with all other factors are maintained, the CTDI is normalized to Sinus 20s (600) protocol at center location	Sinus 10s (300) Sinus 20s (300)	0.50
	CTDI normalized to Sinus 20s (600) protocol at center location	Sinus 10s (150)	0.25
(c)(2)(i)(c)(iii)	CTDI normalized to Sinus 20s (600) protocol at location of maximum CTDI at periphery	Sinus 10s (300) Sinus 20s (300)	0.51
	CTDI normalized to Sinus 20s (600) protocol at location of maximum CTDI at periphery	Sinus 10s (150)	0.26

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(c)(2)(i)(c)(iv)	Dose profile for each selectable nominal tomographic section thickness*.	Please see results above for CTDI values and Section 10.2 for slice sensitivity profiles.	N/A
(c)(2)(i)(c)(v)	A statement of the maximum deviation from these results	All protocols	30%

*The dose profile for each selectable nominal tomographic section thickness is not available because the patient position is fixed throughout the acquisition. The dose profile does not vary across the field of view because of the cone beam geometry. The nominal tomographic section thickness is fixed for each protocol and is not selectable prior to acquisition.

Patient Effective Dose Estimates

Imaging Protocol	Total Effective Dose Estimate (mSv)
Sinus 20s (600)	0.17
Sinus 10s (300)	0.09
Sinus 10s (150)	0.04
T Bone 20s (600)	0.13
Scout View	< 0.01

Legacy Protocols (ISI Source)

The CT conditions of operation used to provide dose and imaging performance information below are as follows:

Sinus 40s (600): 120 kVp, 5 mA, 16 ms pulses, 600 pulses (48 mAs), 10.6 mm Al equivalent fixed filtration, 0.542 ± 0.048 mm tomographic section thickness.

Sinus 20s (300): 120 kVp, 5 mA, 16 ms pulses, 300 pulses (24 mAs), 10.6 mm Al equivalent fixed filtration, 0.547 ± 0.071 mm tomographic section thickness.

Sinus 10s (150): 120 kVp, 5 mA, 16 ms pulses, 150 pulses (12 mAs), 10.6 mm Al equivalent fixed filtration, 0.536 ± 0.130 mm tomographic section thickness.

T Bone 40s (600): 125 kVp, 7 mA, 18 ms pulses, 600 pulses (75.6 mAs), 10.6 mm Al equivalent fixed filtration, 0.532 ± 0.043 mm tomographic section thickness.

The nominal tomographic section thickness is fixed for each protocol and is not selectable prior to

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acquisition.

CTDI Measurements - ISI Source

Protocol	$CTDI_{VOL}$ (mGy)	DLP (mGy-cm)
Sinus 40s (600)	4.5	85.2
Sinus 20s (300)	2.2	42.5
Sinus 10s (150)	1.1	20.6
T Bone 40s (600)	6.0	62.8

Protocol (ISI Source)	**$CTDI_{100}$ (mGy)**				
	Center	Max periphery (8 o'clock position)	Periphery (90° from max)	Periphery (180° from max)	Periphery (270° from max)
Sinus 40s (600)	4.8	4.3	4.2	3.8	3.5
Sinus 20s (300)	2.6	2.1	1.9	1.9	1.9
Sinus 10s (150)	1.3	1.0	1.0	1.0	1.0

Protocol (ISI Source)	**$CTDI_{100}$ (mGy)**				
	Center	Max periphery (2 o'clock position)	Periphery (90° from max)	Periphery (180° from max)	Periphery (270° from max)
T Bone 40s (600)	7.1	5.4	5.4	5.4	5.0

10.6 Installation Requirements

Room Requirements	
Recommended Room Size	8' x 10'
Internet Connectivity	High speed connection is required for service/maintenance.

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Note: The operator of the MiniCAT™ must be able to make visual and audio contact with the patient being scanned while behind radiation barrier.

Power Requirement	**Japan**	**Japan**	**Europe**	**USA**
Line Voltage	~200V	~100V	~220-240V	~115V
Line Frequency	50-60 Hz	50-60 Hz	50-60 Hz	50-60 Hz
Line Current r.m.s (standby) (@ line voltage)	2.5A	5A	2.5A	5A
Line Current r.m.s (max) Measured @ Line voltage, load 125 kVp, 58.8 mAs	5A	10 A	5 A	10 A
Phase	Single	Single	Single	Single
Main Circuit Breaker	5A	10A	5A	10A
MiniCAT input voltage regulation range (measured at UPS output): 100 x $(V_{NO\ LOAD} - V_{LOADED})/V_{LOADED} \leq 2\%$* NB: unit must be used with provided line conditioner (UPS); Do not initiate a scan without AC power to the UPS. * For immunity to electrical noise, a dedicated AC power line with a separate circuit breaker, dedicated neutral and ground is recommended to install a MiniCAT. *A dedicated line is required if the above voltage regulation requirement at the UPS output cannot be met.*				
Line frequency range 47 Hz – 63 Hz				

Note: A dedicated electrical wall outlet with a separate circuit breaker and ground is recommended to protect against electrical noise.

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Environmental Conditions

It is recommended that the MiniCAT™ is operated in a climate-controlled environment where the ambient temperature does not exceed a range of 60 to 75 degrees Fahrenheit. An operating environment where this suggested range cannot be regulated may reduce the expected life cycle of the MiniCAT™ system. Changes in temperature may cause the system to require additional calibration. Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

Operating Requirements	60 to 80 degrees Fahrenheit (16 to 26 degrees Celsius) 10% to 90% humidity
Transportation and Storage Requirements	14 to 104 degrees Fahrenheit (-10 to 40 degrees Celsius) 10% to 90% humidity
Heat Dissipation	Approx. 500W / 1700 BTU/hr

Caution: Allow system temperature to adapt to room temperature before powering up the MiniCAT™ scanner hardware or workstation/server.

Installation/Relocation

The MiniCAT™ cannot be installed or relocated by the user. Proper and safe setup requires specialized training and must be performed by a Xoran Technologies Customer Service Engineer. Call Xoran 1-800-70-XORAN (800-709-6726) for assistance.

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Apparent Resistance of Supply Mains

For the purpose of obtaining the apparent resistance of supply mains on the MiniCAT™ CT system, resistance is determined according to the following formula

$$R = \frac{U_0 - U_1}{I_1}$$

Where:

U_0 is the no-load MAINS VOLTAGE.
U_1 is the MAINS VOLTAGE under load.
I_1 is the mains current under load.

MiniCAT™ CT system utilize single-phase power. Measurements were performed between phase and neutral. Measured results:

U_0 = 121.1V AC
U_1 = 120.7V AC
I_1 = 8.3A

Result: Apparent Resistance of Supply Mains (R) = 0.048 ohms.

MiniCAT Viewing Station Computer Installation Requirements:

It is recommended that the MiniCAT Viewing Station computer when used in a Practice-Examination-Setting be dedicated for MiniCAT software and Patient-Record-Access ONLY (with a workstation class desktop computer).

When a Viewing Station is used on a multi-use computer platform/environment, such as an Administrative Station or a Physician's Office, where a laptop computer may be used, it is recommended that a minimum of additional 3rd Party Software be installed and that anti-virus software be utilized. Xoran cannot assure that the Minimum Requirements, outlined below, will allow 3D Viewing to run optimally as intended.

Component	Minimal Requirements
Operating system	Microsoft Windows 7 Professional, Enterprise and Ultimate editions, both 32 and 64 bits, with any service pack revision (or without a service pack) are supported. Windows 7 Starter and Home editions are not supported. Compatibility with Windows Vista has not been tested. It is recommended to perform an update of Windows Vista to Windows 7 before installing the application. Windows Server (all versions and editions) and Windows 8 are not supported.

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Component	Minimal Requirements
	Linux, Mac OS X or any other non-Microsoft based operating systems are not supported.
CPU	Newer generations of Intel CPU-s including: Intel Pentium D, Intel Core CPU-s (all generations) or later. At least 1.8GHz Intel CPU or faster. AMD processors are not supported. Some MiniCAT features are not compatible with Intel Hyper Threading Technology and they require it to be disabled in the motherboard BIOS. Study reconstruction (if it is ever enabled) is one of these features but reconstruction should not be available to viewing station users by default.
Memory	At least 2GB
Hard drive empty space	At least 200MB of free hard drive space for setup. At least 500MB free hard drive space for the application execution (for temporary data storage). Additional free hard drive space is required for normal functioning of operating system. This space may vary depending of the operating system installed (e.g. 1GB for Windows 7). For example, MiniCAT workstation that is running Windows 7 will require at least: 200MB+500MB+1GB=1.7GB of free hard drive space.
Graphics card	**Xoran Verified Graphics Card and Drivers:** Nvidia GeForce GTS 250; GTS 450; GT 560. Nvidia Drivers: 275.33; 296.10 Note: Above Graphics Cards designed for Desktop Computers (NOT Laptops) due to physical size and dimensions of card. **General Minimum Specifications (applies to laptops as well):** Video card with at least 128MB memory is required. The latest available official version of video drivers. The MiniCAT 3D Viewing feature requires a 256MB video card with hardware support for OpenGL and 3D textures. Depending on the video card model and driver implementation, this General Minimum Specification might not be sufficient for 3D to work as intended. **Xoran does not assure 3D Viewing will work, as intended to, even when the computer system configuration fulfills the General Minimum Specification (not all video card Brands, Models and Driver implementations are developed to the exact same specifications).**

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Component	Minimal Requirements
Optical drive	An optical drive with recording capability is required for burning exported images to CD or DVD.
Network	Fast network card is required (100Mb/s or more). The computer should be able to reach Xoran dedicated router through local network.
USB port	An available USB port is required for HASP key provided by Xoran.
Printer	A local or network printer is required in order to print image reports.

10.7 IGS Compatibility

The following tables summarize the compatibility of MiniCAT™ with other image guided systems.

GE	
Platform	**Compatible with Xoran**
IT3500+, ENTrak+, ConneCTstat+	Yes
IT3500, ENTrak, ConneCTstat	No
IT3000	No
IT2000	No

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Medtronic/LandmarX/Xomed	
Platform	**Compatible with Xoran**
LandmarX Evolution, LandmarX Evolution Plus, LandmarX Element	Yes
LandmarX gen1, LandmarX gen2	No
Medtronic Stealth, Treon, Ion, Tria	No
Medtronic Treon Plus (w/ ENT software), Tria Plus (w/ ENT software)	Yes
Medtronic Fusion	Yes

BrainLAB (Requires Pac Xfer Version 5.2 or Higher)	
Platform	**Compatible with Xoran**
VectorVision	Yes
VectorVision2	Yes
VectorVision Compact (for ENT)	Yes
Kolibri	Yes

Stryker	
Platform	**Compatible with Xoran**
Stryker Navigation System (original)	Yes
NavII	Yes
mNAV	Yes

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11.0 QUALITY CONTROL TESTS

Overview

Xoran encourages MiniCAT™ owners to develop a quality control program with the assistance of a qualified medical physicist. In this section, we recommend some tests which can be included in the program.

MiniCAT™ owners participating in an MiniCAT™ service agreement are eligible to receive assistance performing these test procedures from Xoran Customer Service personnel. However, Xoran recommends (and your state may require) that a medical physicist perform an independent evaluation. Xoran provides a quality control phantom to use for these quality control tests.

Xoran has developed these procedures to scan only the sinuses and temporal bones, which are high-contrast or 'bone window' imaging tasks that require isotropic high spatial resolution and do not require the level of contrast resolution needed for other imaging tasks, such as brain or muscle tissue scanning, etc. Xoran designed the MiniCAT™ according to the ALARA (As Low As Reasonably Achievable) principle by minimizing the radiation dose to the patient while providing the image quality necessary for scanning the sinuses and temporal bones.

Should your MiniCAT™ system fail any of the following quality control tests, contact Xoran Customer Service at (800) 70-XORAN for corrective action.

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Manufacturer Recommended Frequency of QC Tests		
Section	**Test**	**Frequency**
11.1	Laser Accuracy	Monthly
11.2	CT Number of Reference Materials	Monthly
11.3	Spatial Resolution	Monthly
11.4	CT Number and Standard Deviation of Water	Daily
11.5	Artifact Test	Daily
11.6	Uniformity Test	Monthly
11.7	Contrast Scale	Annually
11.8	Image Noise	Annually
11.9	Nominal Tomographic Section Thickness and Slice Sensitivity Profile	Annually

Note: The required frequency of QC tests may vary according to state regulations, accrediting organizations, or your medical physicist.

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The Quality Control Phantom:

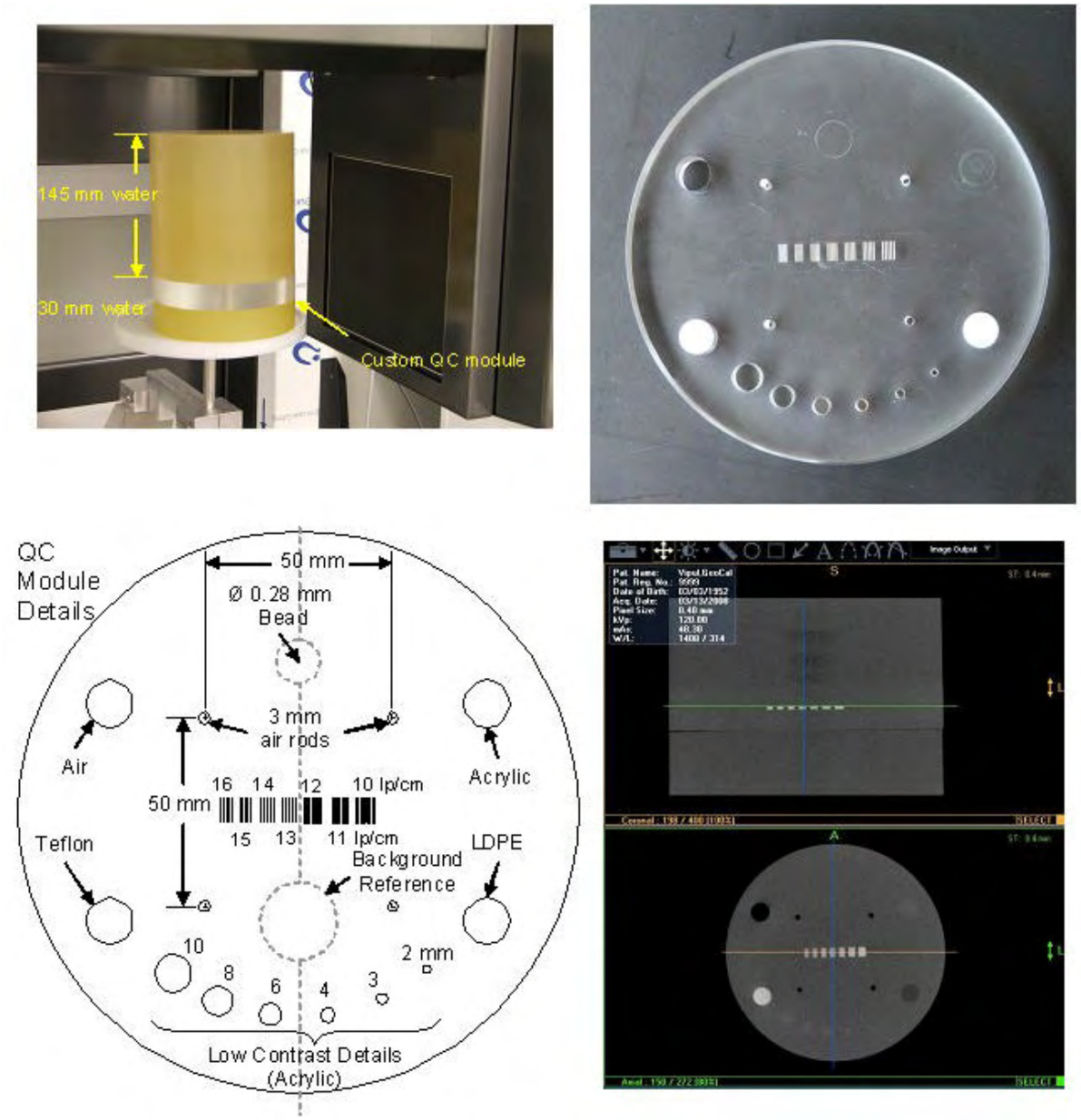

Fig. 5. Top Left: the QC Phantom and the Custom QC and Uniformity Material modules in the MiniCAT. Top Right: Photo of the QC Module. Bottom Left: Simplified drawing of the QC Module. Bottom Right: Coronal and Axial images of an MiniCAT scan of the QC phantom.

Procedure:

Before QC is conducted, a Daily Calibration should be performed.

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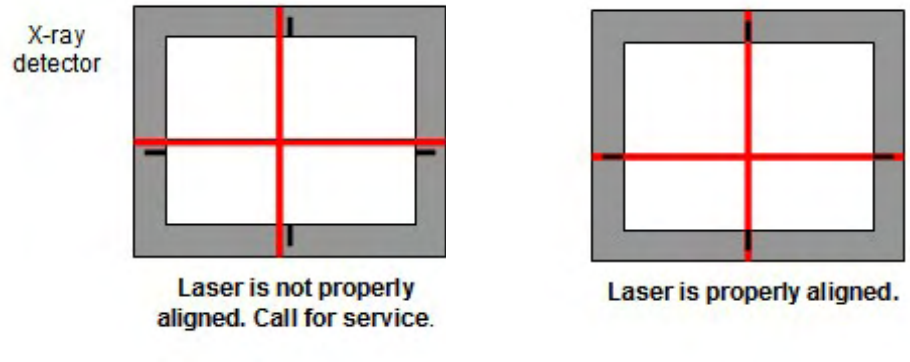
1. Scan the QC Phantom with the QC module placed on the central slice, the Front label facing forward, and the entire module placed centrally in the field of view. Scan the phantom with the appropriate protocol(s) specified in the respective QC test.

11.1 Laser Accuracy

To confirm alignment light accuracy:

1. Press and hold the **Alignment Light** button on the controller to turn on laser.

- Press button once to turn on the laser for a few seconds.
- Press and hold for three seconds to turn on the laser for five minutes.
- Side lasers should align with the alignment stickers on perimeter of X-ray detector.



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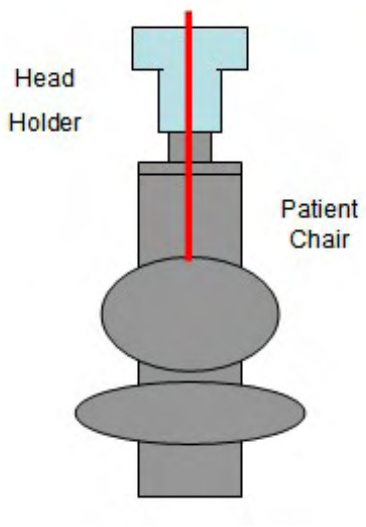
- Front laser should hit the center of the headrest and/or gantry.



11.2 CT Number of Reference Materials

Equipment and Scan: Quality Control Phantom, Resolution QC scan

Procedure:

1. Using the Resolution QC scan, scroll to the midpoint of the four reference material inserts (Teflon, LDPE, Acrylic, Air) in the axial view of the reconstructed QC Phantom scan.
2. Draw a circular region entirely within each of the reference material boundaries. Each circular region should range in size from 65-80 square millimeters.
3. Record the mean value for each material and compare with the acceptable range for each.

Tolerance:

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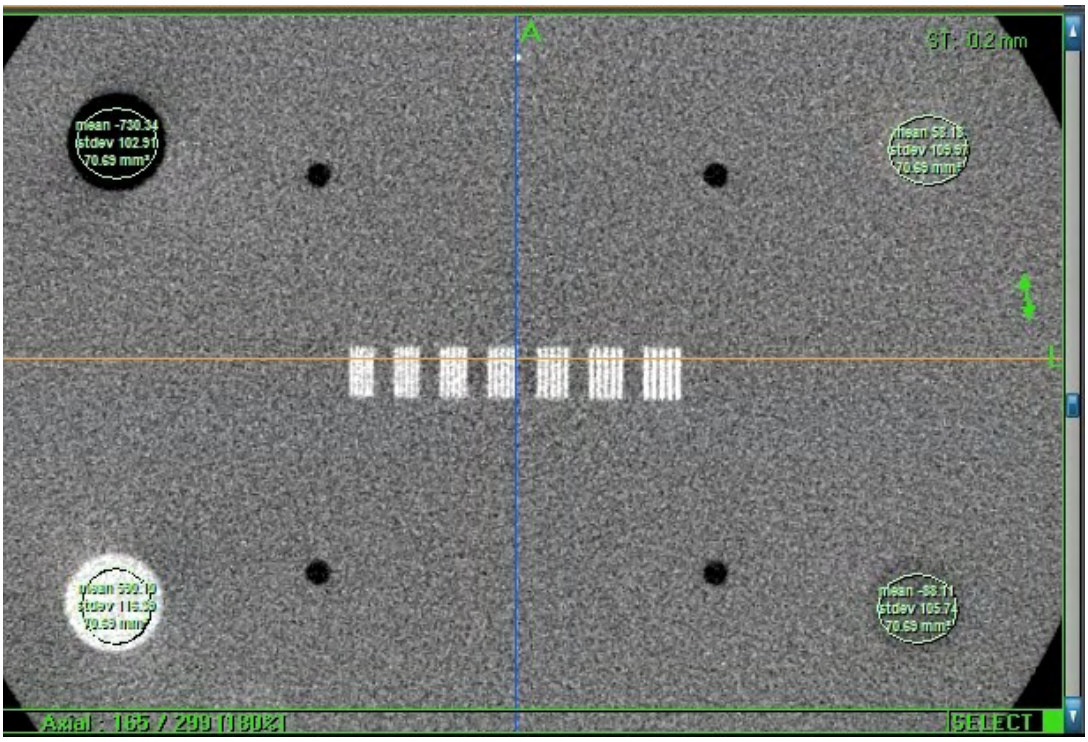
Air -1000 to -650 HU

Teflon >550 HU

Acrylic 50 to 250 HU

LDPE -200 to 0 HU



11.3 Spatial Resolution

Equipment and Scan: Quality Control Phantom, Resolution QC scan

High Contrast Procedure:

1. Using the Resolution QC scan, position the Quality Control phantom at the central slice.

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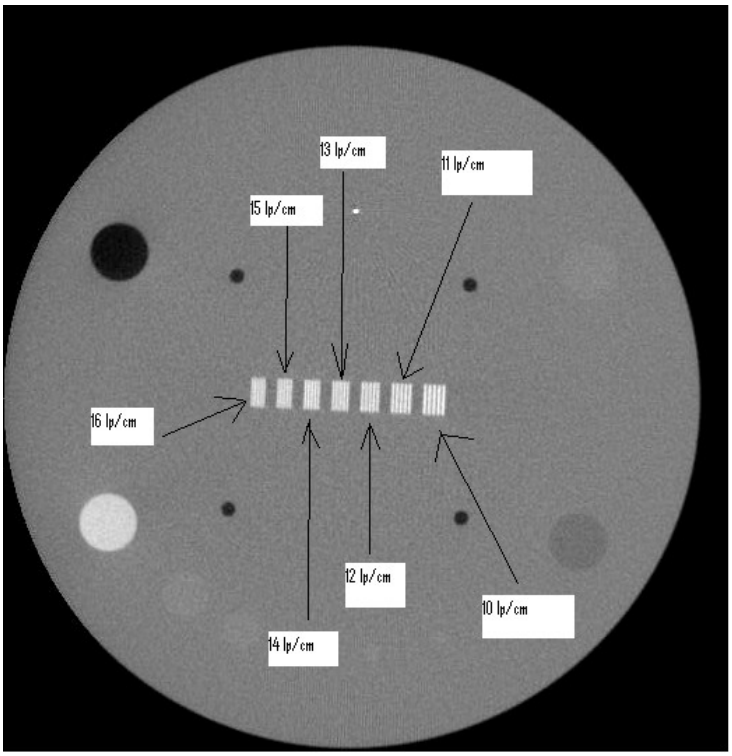
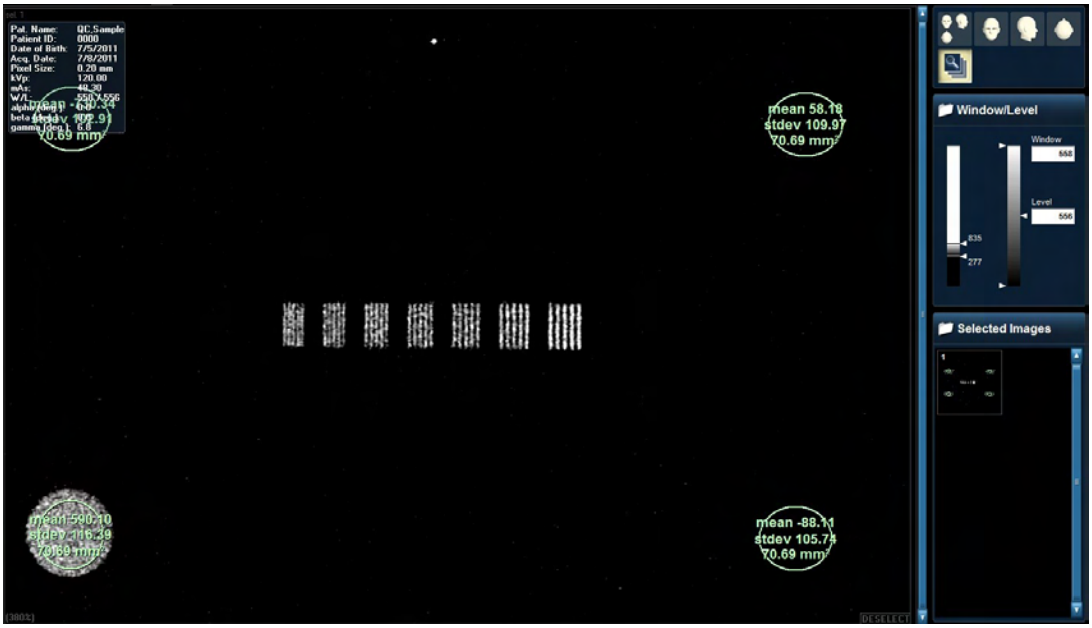
2. To verify high contrast resolution, scroll to the graded line pair targets in the axial view of the reconstructed scan and adjust the window level and zoom level to achieve good viewing characteristics of the graded line pairs (see picture below).



The picture below is an example of a typical window level for accurate lp/cm viewing.



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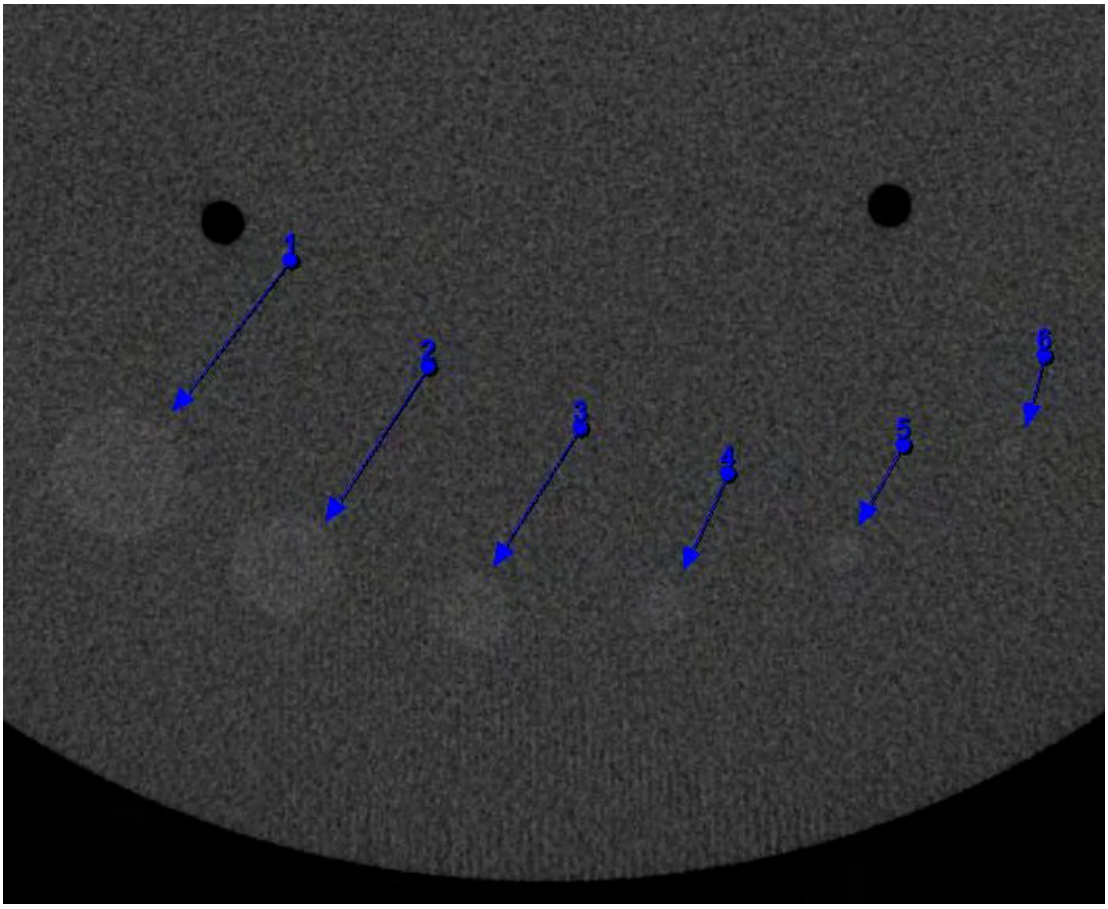
3. Record the highest number of line pairs visually determined to be well distinguishable, and compare with the tolerance below.

Tolerance: The line pair pattern of 15 lp/cm should be distinguishable.

Low Contrast Procedure:

1. Scroll to the six low contrast targets of the QC Module made of HDPE of sizes 10, 8, 6, 4, 3, and 2 mm diameter in the axial view of the reconstructed scan.

2. Adjust the window level, zoom level and slice thickness (if necessary) to achieve good viewing characteristics of all six targets.



Tolerance: Greater or equal to 4 targets should be distinguishable.

11.4 CT Number and Standard Deviation of Water

Equipment and Scan: Quality Control Phantom, Water Calibration protocol.

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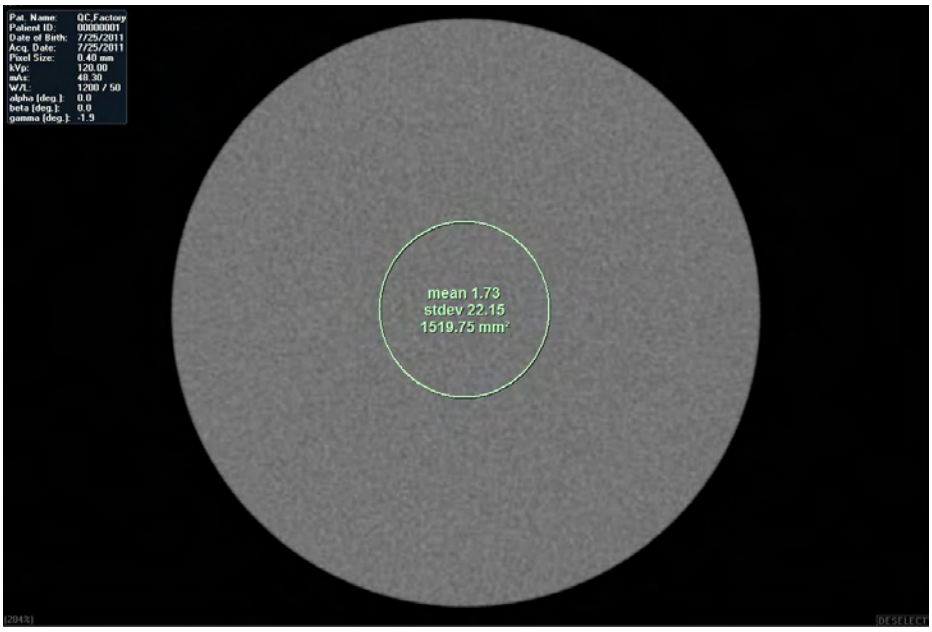
Procedure:

1. Scroll axially approximately 2 cm above the QC module to the large section of the water module.
2. Select a region centered on the axial view of the disk, make the region approximately 1500 sq. mm.
3. Record the STD and Mean values for water and compare with the tolerance below.

Tolerance: STD of water $\leq$ 30, Mean ± 100 HU



11.5 Artifact Test

Equipment and Scan: Quality Control Phantom, Water Calibration protocol.

Procedure:

1. To look for ring artifacts in the image, start at one axial extreme of the reconstructed QC Phantom scan and scroll through all slices to the other extreme looking at each axial slice. (Ensure that no rotations of the data have been applied – i.e.: restore original tilts.) The image below represents artifacts that are visible in a reconstruction. This may indicate the need for offset and gain calibration.

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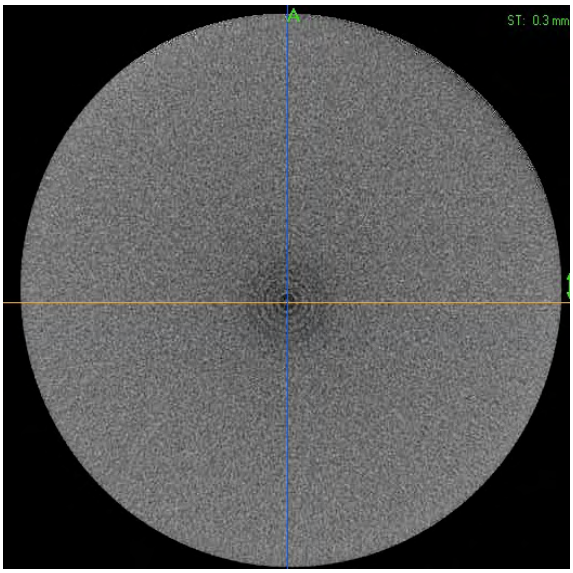

Tolerance: The images should be free from artifacts.

11.6 Uniformity Test

Equipment and Scan: Quality Control Phantom, Water QC scan

Procedure:

1. Scroll axially approximately 2 cm above the QC Module to the large section of the Water Module.

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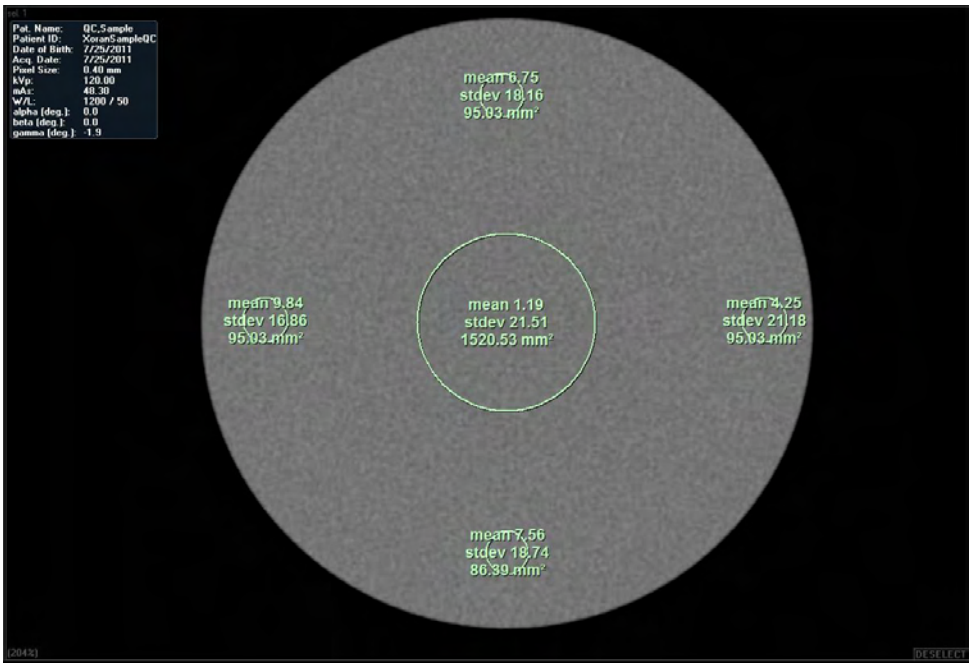
2. Draw four more circular regions (in addition to the 1500 sq. mm region) at the approximate locations as show. Each region should range in size from 90 to 110 sq. mm.



3. Compare the mean values of each region and record the minimum and maximum values.

4. Compare the total range with the tolerance below.

Tolerance: The total range for mean values must be within or equal to ± 50 HU.

11.7 Contrast Scale

Equipment and Scan: 2 30 mm Water Modules, Sinus 20s (600), Sinus 10s (300), Sinus 10s (150), T Bone 20s (600)

Procedure:

1. Acquire a Scout for Sinus 20s (600), Sinus 10s (300), Sinus 10s (150). Label these scans "*Contrast Scan 1.*"

2. Place a 30 mm Water Module over the source. The 30 mm water module should be centered over the aperture of the source. The 30 mm water module can be attached to the gantry with strong tape, but make sure the tape will not be blocking any part of the x-ray beam.

3. Acquire a Scout for T Bone 20s (600). Label this scan "*Contrast Scan 1*" as well.

4. Acquire a Scout for Sinus 20s (600), Sinus 10s (300), Sinus 10s (150). Label these scans "*Contrast Scan 2.*"

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5. Place a second 30 mm Water Module over the first.
6. Acquire a Scout for T Bone 20s (600). Label this scan "*Contrast Scan 2*" as well.
7. Remove one 30 mm Water Module so one is still in place.
8. Acquire a Scout for T Bone 20s (600). Label this scan "*Contrast Scan 3*."
9. Remove the remaining 30 mm Water Module.
10. Acquire a Scout for Sinus 20s (600), Sinus 10s (300), Sinus 10s (150). Label these scans "*Contrast Scan 3"* as well.
11. Open a scout view of one of the sinus scans.
12. Select Show Ruler from the Toolbox. Zoom in to align the edges of the Scout with the ruler tick marks.
13. Open the Study Details and note the Central slice [pixel] value.
14. Using the Distance Tool, draw a horizontal line across the scout Y value that matches the Central slice [pixel] value.
15. Using the Distance Tool, draw a vertical line centered horizontally across the scout.
16. Create a circular region of 100 mm^2 (± 20 mm^2) centered at the crosshairs.

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17. Record mean value of the region in the appropriate section of the User QC Spreadsheet.

18. Go to tool box, and click “Save Planning File” and save as “Sinus Contrast.”

19. Open each sinus scout, load the planing file and record the mean value of the region in the appropriate section of the User QC Spreadsheet.

20. Open the Scout of a temporal bone Scout.

21. Repeat steps 12-16 for the temporal bone Scout.

22. Go to tool box and click “Save Planning File,” and save as “T-Bone Contrast.”

23. Open each temporal bone Scout, load the planing file and record the mean value of the region in the appropriate section of the User QC Spreadsheet.

24. Using the Attenuation Table below, lookup the nearest attenuation value for water, and trace the row right to find the Teflon-Water Differential Δ°. Record this number in the appropriate section of the User QC Spreadsheet. If the water attenuation value corresponds to more then one energy (multiple table rows), record the mean value of the Teflon-Water Differential.

Attenuation units: [cm^{-1}]

Energy	Water	Teflon	Teflon-Water

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[keV]	(Uniformity Material)		Differential [Δμ]
60	0.203	0.406	0.203
61	0.202	0.402	0.2
62	0.201	0.397	0.196
63	0.2	0.395	0.195
64	0.199	0.391	0.192
65	0.198	0.389	0.191
66	0.197	0.384	0.187
67	0.196	0.382	0.186
68	0.196	0.38	0.184
69	0.195	0.376	0.181
70	0.194	0.374	0.18
71	0.193	0.372	0.179
72	0.192	0.369	0.177
73	0.192	0.367	0.175
74	0.191	0.365	0.174
75	0.19	0.363	0.173
76	0.189	0.361	0.172
77	0.189	0.359	0.17

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78	0.188	0.356	0.168
79	0.187	0.354	0.167
80	0.187	0.352	0.165
81	0.186	0.35	0.164
82	0.186	0.35	0.164
83	0.184	0.348	0.164
84	0.183	0.346	0.163
85	0.183	0.343	0.16
86	0.182	0.343	0.161
87	0.182	0.341	0.159
88	0.181	0.339	0.158
89	0.181	0.339	0.158
90	0.18	0.337	0.157

25. Scan the QC Phantom with the QC module placed on the central slice, the Front label facing forward, and the entire module placed centrally in the field of view. Scan the phantom with Sinus 20s (600), Sinus 10s (300), Sinus 10s (150), and T Bone 20s (600).

26. Open the Sinus 20s (600) reconstruction, and locate the central slice (click Study Details. The central slice is the opposite of zmin). Draw a 65-80 mm^2 circular region within the Teflon material insert.

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27. Record the Teflon mean value in the CT_x section of the User QC Spreadsheet.

28. Record the coordinates (X, Y) of center of the Teflon region in the (X,Y) section of the User QC spreadsheet. (NOTE: The coordinates are located in the upper-right region of the MPR window.)

29. Scroll axially in the superior direction about 3 cm to the Water Module of the QC Phantom. Draw a 65-80 mm^2 circular region at (approximately) the same (X,Y) location. Record the mean value in this region in the CT_w Section of the User QC Spreadsheet.

30. Repeat Steps 26-29 for Sinus 10s (300), Sinus 10s (150), and T Bone 20s (600).

Tolerance:

Sinus 20s (600): 0.00023 to 0.00034

Sinus 10s (300): 0.00021 to 0.00041

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Sinus 10s (150): 0.00021 to 0.00037

T Bone 20s (600): 0.00019 to 0.00036

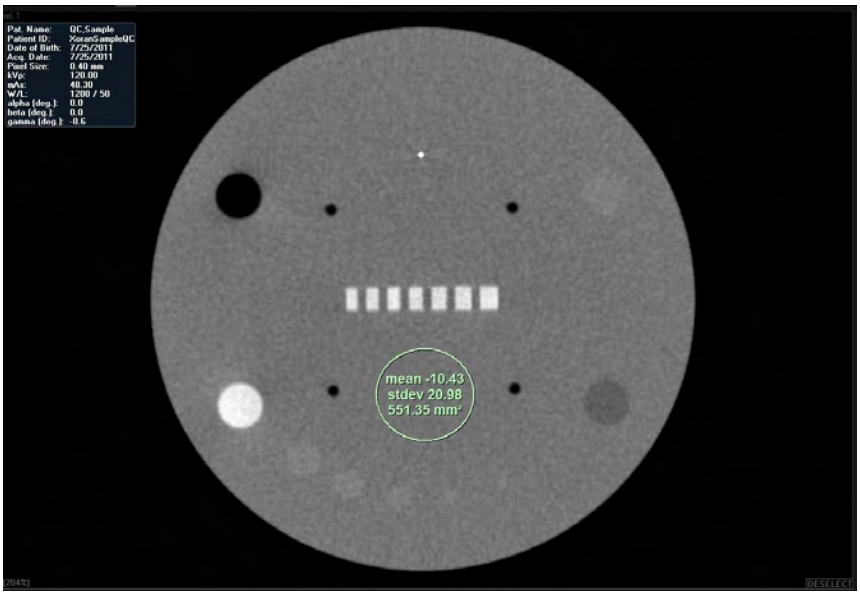
11.8 Image Noise

Equipment and Scan: Quality Control Phantom, Sinus 20s (600), Sinus 10s (300), Sinus 10s (150), T Bone 20s (600)

Procedure:

1. Draw a circular region of 550 mm^2 (± 20mm^2) in the background reference area of the QC module, centered left to right and below (top to bottom) the line pairs of the phantom in a uniform region.

2. Record the standard deviation, S(measured). in the appropriate cell of the User QC Spreadsheet. Note that Contrast Scale must be performed before the Image Noise test.



3. Repeat these steps for each of the clinical scans.

Tolerance:

Sinus 20s (600): 1.88 to 3.87

Sinus 10s (300): 2.69 to 7.04

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Sinus 10s (150): 4.49 to 9.69

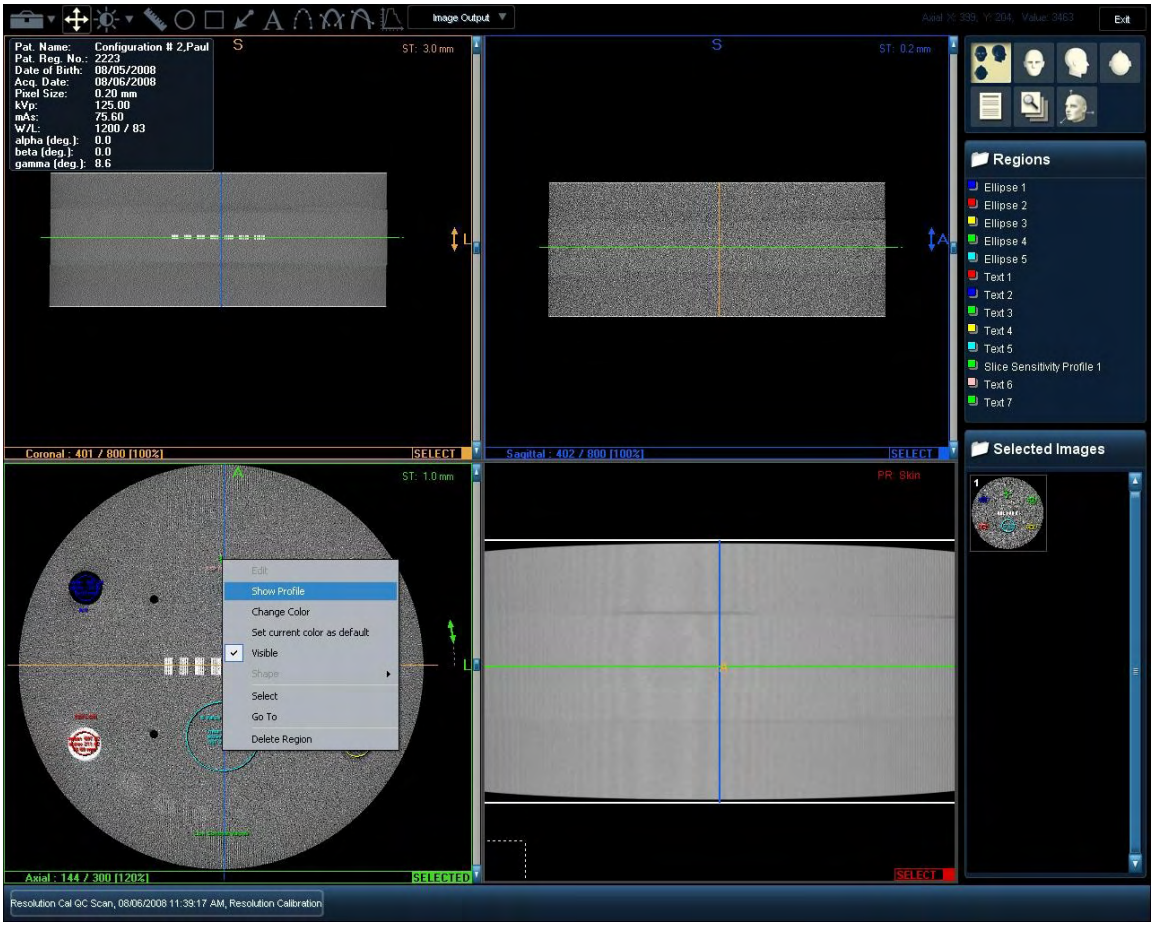
T Bone 20s (600): 3.54 to 7.91

11.9 Nominal Tomographic Section Thickness and Slice Sensitivity Profile

Equipment and Scan: Quality Control Phantom, Sinus 20s (600), Sinus 10s (300), Sinus 10s (150), T Bone 20s (600)

Measuring Nominal Tomographic Section Thickness is obtained by finding the full-width half-maximum (FWHM) resolution of the Slice Sensitivity Profile (SSP). The SSP is obtained by scanning a small, sub-voxel bead in the QC module. Specifically, the custom QC module contains a 0.280 mm tungsten bead in the upper half of the phantom.

Note: See below picture as reference.



Procedure:

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1. Find the tungsten bead in the axial direction of the Sinus 20s (600) scan.
2. Select the Slice Sensitivity Profile tool from the Toolbox menu.
3. Place SSP selection on the center of the tungsten bead.
4. Right click SSP selection and select "Show Profile."
5. If a warning appears (for poor signal, not enough samples, or poor centering), center SSP selection tool on tungsten bead again.
6. Record the Width value reported by the software in the SSP (measured) row of the User QC spreadsheet.
7. Repeat these steps for the Sinus 10s (300), Sinus 10s (150), T Bone 20s (600) and compare with the tolerances below.

Tolerance:

Sinus 20s (600): 0.494 to 0.589

Sinus 10s (300): 0.476 to 0.618

Sinus 10s (150): 0.406 to 0.665

T Bone 20s (600): 0.489 to 0.574

Note: Failure to be within these ranges implies poor geometric calibration or mechanical problems with the device.

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